

REMARKS

A request for continued examination (RCE) accompanies this Amendment.

Claims 26-39, 33-35, and 37-46 and as amended are directed to the elected claimed method. Claims 26-39, 33-35, 37, and 44-46 require the feature of indicating the percent daily value of vitamin C in the dose of ibuprofen.

The elected claimed method and the steps of the elected claimed method and the functional relationship needed by the elected claimed method are not disclosed in the prior art of record. SS Pharmaceutical, Tsunoda, and Yeh et al and Krause teach away from the elected claimed method and its desired results. The prior art of record does not disclose a method of monitoring consumption of vitamin C nutritional supplement with ibuprofen discomfort reliever, or the steps of the elected claimed method of labeling indicating the amount and percent daily value of vitamin C in a dose of ibuprofen, consuming the dose from the labeled enclosure, and monitoring amount of the vitamin C consumed.

CLAIMED METHOD IS NOT DISCLOSED, BUT IT IS TAUGHT AWAY FROM, AND IT SATISFIES A LONG FELT NEED

The elected claimed method of monitoring consumption of vitamin C nutritional supplement with ibuprofen discomfort reliever labels the amount and percent daily value of vitamin C nutritional supplement in a dose of ibuprofen discomfort reliever. It provides a functional relationship between the labeling and the vitamin C nutritional supplement in the dose. It monitors the vitamin C nutritional supplement consumed with the ibuprofen discomfort reliever. And, it desirably results in enabling regulation of the vitamin C nutritional supplement consumed with ibuprofen discomfort reliever.

The combination of SS Pharmaceutical, Tsunoda, and Yeh et al and Krause is improper, because nothing is disclosed or taught in them to suggest their combination [see Section I below]. The combination of SS Pharmaceutical, Tsunoda, Yeh et al, and Krause does not have a reasonable expectation of success in arriving at the elected claimed method, since they do not disclose

monitoring vitamin C consumed with ibuprofen or any of the steps of the elected claimed method [see Section I below]. It would not have been obvious to use an antioxidant in a dose of ibuprofen as a nutritional supplement in a dose of ibuprofen, since it changes its operation from an antioxidant to prevent oxidation of ibuprofen in a dose of ibuprofen, to supplementing nutrition of the consumer of the dose of ibuprofen [see Section I below]. No amount or percent daily value of antioxidant is indicated in labeling of commercially available ibuprofen, and the prior art of record does not disclose labeling indicating an amount or percent daily value of antioxidant [see Section I below]. Yeh et al, SS Pharmaceutical, Tsunoda and Krause do not disclose, inherently provide, or enable the elected claimed method, its steps, or its desired results [see Section II below]. And, they do teach away by not enabling the elected claimed method, its steps, or its desired results [II]. The elected claimed method solves problems, and it satisfies needs felt for decades of ibuprofen consumption [II]. The elected claimed method of monitoring the consumption of vitamin C with ibuprofen, is not obvious, since neither the method nor its steps of a) labeling an amount and percent daily value of vitamin C in a dose of ibuprofen, b) consuming the dose from the labeled product, and c) monitoring the amount of the vitamin C consumed with ibuprofen, are disclosed, inherently provided, or enabled by Yeh et al, SS Pharmaceutical, Tsunoda and Krause [III]. The elected claimed method requires a product having labeling indicating the amount and percent daily value of vitamin C in a dose of ibuprofen, and the steps of labeling an enclosure with labeling indications indicating the amount and percent daily value of the vitamin C in a dose of ibuprofen, consuming the dose, and monitoring the vitamin C consumed, and it produces the useful result of enabling the consumer to regulate consumption of the vitamin C, which are not disclosed by Yeh et al, SS Pharmaceutical, Tsunoda and Krause [III]. Yeh et al, SS Pharmaceutical and Tsunoda do not disclose a product having labeling indicating the percent daily value of vitamin C in a dose of ibuprofen, as required by the claimed method [IV]. While Krause teaches food labeling, Krause does not teach a method of monitoring vitamin C consumed with ibuprofen, or any of the steps of

the claimed method of a) labeling the amount and percent daily value of vitamin C in a dose of ibuprofen, which provides a functional relationship with vitamin C in the dose of ibuprofen, that enables monitoring vitamin C consumption with ibuprofen, b) consuming the dose from the product labeled, and c) monitoring the amount of vitamin C consumed with ibuprofen [V]. While Krause teaches food labeling, Krause does not disclose a dosage form for ibuprofen and vitamin C, or labeling a product for a dose of ibuprofen and vitamin C, or labeling which is functionally related to the amount or percent daily value of vitamin C in a dose of ibuprofen, or a method for monitoring vitamin C consumed in a dose of ibuprofen, or monitoring vitamin C consumption with ibuprofen, as provided by the elected claimed method [VI]. It would not have been obvious to one of ordinary skill in the art at the time of the invention to monitor vitamin C consumed in a dose of ibuprofen, as provided by the elected claimed method, while administering the ibuprofen composition of Yeh et al, (or SS Pharmaceutical or Tsunoda) for treating pain, since they do not disclose monitoring consumption of vitamin C, or enable it [VII]. Labeling of commercial ibuprofen does not indicate any percent daily value or amount of antioxidant, vitamin C or nutritional supplement [VIII]. Monitoring vitamin C consumption, as provided by the elected claimed method, would not be obvious to one of ordinary skill in the art at the time of the invention, by administering the ibuprofen composition of the ibuprofen prior art of record or commercially available ibuprofen products for treating pain (Attachments B and C), since they do not disclose labeling an amount of vitamin C in a dose of ibuprofen, or a functional relationship between labeling and vitamin C in a dose of ibuprofen, which are needed to monitor vitamin C consumption [VIII]. It would not have been obvious to one of ordinary skill in the art to employ the monitoring step of the elected claimed method, since the prior art of record does not disclose 1) monitoring consumption of vitamin C (or any other nutritional supplement) consumed with ibuprofen, or 2) labeling the amount and percent daily value of vitamin C (or any other nutritional supplement) in a dose of ibuprofen and 3) a functional relationship between the labeling and the vitamin C (or any other nutritional supplement) in a dose of ibuprofen, which are needed to

enable monitoring vitamin C consumed with ibuprofen [IX]. One of ordinary skill in the art having been motivated to administer the analgesic composition of Yeh et al, (or SS Pharmaceutical or Tsunoda) for treating pain, would not have been motivated to regulate vitamin C consumption, since it is not disclosed, or enabled [X]. Administering a composition of Yeh et al, SS Pharmaceutical or Tsunoda does not inherently provide or enable a method of monitoring vitamin C consumption, or any of the steps of the elected claimed method of a) labeling the amount and percent daily value of the vitamin C in a dose of ibuprofen, b) consuming the dose from the labeled enclosure and c) monitoring the amount of the vitamin C consumed [XI]. Applicant is entitled to patent the elected claimed method for monitoring consumption of vitamin C with ibuprofen by labeling a known composition, consuming a dose from the labeled product, and monitoring the vitamin C consumed, since i) the elected claimed method, its steps and the functional relationship needed to carry it out are not disclosed by the prior art of record, ii) the prior art of record teaches away from the claimed method, iii) the elected claimed method satisfies a long felt need, and iv) the claimed method solves the problem, which others have failed to solve of not being able to monitor or regulate vitamin C consumption from consuming ibuprofen pain reliever, containing vitamin C antioxidant, or make the invention of the elected claimed method [XII]. One of ordinary skill in the art would not have been motivated to employ the step of monitoring of vitamin C, since the labeling system of the ibuprofen pain reliever prior art is not intended for patients to grasp and understand the daily regimen of regulating consumption of vitamin C nutritional supplement and thereby improve the adherence to the daily regimen [XIII]. Accordingly, the Claims are not obvious under 35 USC 103 over the prior art of record, as its steps are not disclosed by the prior art of record, which teach away, and the defects in use for decades are cured by the claimed method, the previously unknown practical uses given by the claimed method, the failure of others to find a solution to the problem of not being able to monitor or regulate vitamin C consumption from consuming ibuprofen pain reliever, or make the invention of the claimed method.

LACK OF ANY TEACHING FOR A COMBINATION OF REFERENCES

[Section I] The combination of SS Pharmaceutical, Tsunoda, and Yeh et al and Krause is improper, because nothing is disclosed or taught in them to suggest their combination. The combination of SS Pharmaceutical, Tsunoda, Yeh et al, and Krause does not have a reasonable expectation of success in arriving at the elected claimed method, since they do not disclose monitoring vitamin C consumed with ibuprofen or any of the steps of the elected claimed method. It is not obvious to use an antioxidant in a dose of ibuprofen as a nutritional supplement in a dose of ibuprofen, since it changes its operation from an antioxidant to prevent oxidation of ibuprofen in a dose of ibuprofen, to supplementing nutrition of the consumer of the dose of ibuprofen. No amount or percent daily value of antioxidant is indicated in labeling of commercially available ibuprofen, and the prior art of record does not disclose labeling indicating an amount or percent daily value of antioxidant.

The court has stated that a teaching is required in the references to suggest the combination thereof for a proper combination of references, In re Sernaker 702 F2d 989, 217 U.S.P.Q. 1 (CAFC, 1983). No teaching is provided by Yeh et al, SS Pharmaceutical, Tsunoda or Krause to suggest their combination, so the combination thereof is improper. The elected claimed method of monitoring consumption of vitamin C nutritional supplement with ibuprofen discomfort reliever, has steps of labeling indicating the amount and percent daily value of vitamin C in a dose of ibuprofen and consuming the dose from the label enclosure and monitoring consumption of the vitamin C. SS Pharmaceutical, Tsunoda, and Yeh et al disclose ibuprofen. They do not disclose a method of monitoring consumption of vitamin C nutritional supplement with ibuprofen discomfort reliever, any of its steps of labeling indicating the amount and percent daily value of vitamin C in a dose of ibuprofen and consuming the dose from the label enclosure and monitoring consumption of the vitamin C in the dose of ibuprofen. Krause discloses nutrition labeling for food, but does not disclose ibuprofen or discomfort relievers. Since, Yeh et al, SS Pharmaceutical, and Tsunoda, do not disclose a method of monitoring consumption of vitamin C with ibuprofen, or any of the steps of the elected claimed method, and Krause does not disclose ibuprofen or discomfort relievers, there is no teaching to

suggest their combination to show obviousness of the elected claimed method. Thus, the combination of SS Pharmaceutical, Tsunoda, and Yeh et al and Krause is improper, because nothing is disclosed or taught in them to suggest their combination, In re Sernaker. Accordingly, the Claims are not obvious over SS Pharmaceutical, Tsunoda and Yeh et al and Krause.

The court has stated that a teaching or suggestion to make the claimed combination and a reasonable expectation of success must both be found in the prior art, not in Appellant's disclosure In re Vaeck 947 F 2d 488, 20 USPQ2d 1438 (Fed. Cir 1991). The prior art of record lacks both a teaching to make the claimed combination and a reasonable expectation of success. Nothing is taught in SS Pharmaceutical, Tsunoda, Yeh et al and Krause to suggest their combination, so their combination is improper, In re Sernaker. And, there is not a reasonable expectation of success for monitoring vitamin C consumed with ibuprofen based on SS Pharmaceutical, Tsunoda, and Yeh et al, since they do not disclose monitoring vitamin C consumed with ibuprofen or any of the steps of the elected claimed method. And, Krause does not disclose ibuprofen. Additionally, they teach away from supplementing nutrition, as discussed below. So, the combination of SS Pharmaceutical, Tsunoda, Yeh et al, and Krause does not have a reasonable expectation of success in arriving at the elected claimed method, since they do not disclose monitoring vitamin C consumed with ibuprofen or any of the steps of the elected claimed method. Accordingly, the Claims are patentable under 35 USC 103 over SS Pharmaceutical, Tsunoda, Yeh et al and Krause.

A proposed modification cannot change the principle of operation of a reference, MPEP 2143.01. VI, and In re Ratti 270 F 2d 810, 123 USPQ 349 (CCPA 1959). Yeh et al (column 2, lines 31-33), SS Pharmaceutical, and Tsunoda disclose vitamin C as an antioxidant to reduce oxidation in a dose of ibuprofen. Krause disclose vitamin C as to supplement nutrition of the consumer (page 277). So, it would not have been obvious to use an antioxidant in a dose of ibuprofen as a nutritional supplement in a dose of ibuprofen, since it changes its operation from an antioxidant to prevent oxidation of ibuprofen in a dose of ibuprofen, to supplementing nutrition of the consumer of the dose of ibuprofen.

Thus, it would not have been obvious to use vitamin C in a dose of ibuprofen as a nutritional supplement, since it changes the principle of operation, MPEP 2143.01. VI, and In re Ratti. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause, since the proposed modification changes the principle of operation.

The Prior Art And Commercial Ibuprofen Labeling Do Not Indicate Amount (or % Daily Value) of Antioxidant

The court has stated that rejections on obviousness cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness, In re Kahn 441 F3d 977, 988, 78 U.S.P.Q. 2d 1329, 1336 (Fed. Cir. 2006), MPEP 2143.01, section IV. SS Pharmaceutical, Tsunoda, Yeh et al and Krause do not disclose labeling indicating any amount (or percent daily value) of an antioxidant, such as vitamin C, in an ibuprofen product. And, they do not disclose monitoring consumption of any amount (or percent daily value) of an antioxidant, such as vitamin C, in an ibuprofen product. Antioxidants added to ibuprofen do not need to be nutritional supplements, see US Patent 5185373 column 2, lines 25-53, see Attachment A. Some commercially available ibuprofen (Motrin) does not include an antioxidant, see Attachment B. The labeling does not indicate an amount for any ingredient, except ibuprofen. Some commercially available ibuprofen (Advil) labeling lists (under inactive ingredients) sodium benzoate, which is a preservative and antioxidant, see Attachments C and D. And, the labeling does not indicate an amount for the antioxidant or any other ingredient, except ibuprofen. Also, the labeling does not indicate a percent daily value for antioxidant, or any other ingredient. So, no amount or percent daily value of antioxidant is indicated in labeling of commercially available ibuprofen, and the prior art of record does not disclose labeling indicating an amount or percent daily value of antioxidant. Thus, stating that labeling the amount of antioxidant vitamin C in a dose of ibuprofen would be obvious is a mere conclusory statement, and inconsistent with commercially available ibuprofen; instead there must be some articulated reasoning, In re Kahn.

Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause, since they do not articulate reasoning to support the conclusion.

CLAIMED METHOD NOT DISCLOSED BY ART, WHICH TEACHES AWAY
[Section II] All of the features of the claimed invention must be shown to establish *prima facie* obviousness of the invention, In re Royka, 490 F2d 981, 180 USPQ 580 (CCPA 1974), MPEP 2143.3. There is no teaching to establish a *prima facie* case of obviousness, if a reference teaches away from (2) a path taken or (3) a result sought by the applicant, Tec Air. The claimed method of monitoring consumption of vitamin C with ibuprofen, labels the amount and percent daily value of vitamin C in a dose of ibuprofen, and provides a functional relationship between labeling and vitamin C in a dose of ibuprofen (enabling monitoring vitamin C consumption), and monitors the vitamin C consumed. Monitoring vitamin C consumed enables regulating it. Yeh et al, SS Pharmaceutical, Tsunoda and Krause do not disclose, inherently provide, or enable the claimed method, its steps, or its desired results. They do not disclose labeling an amount and percent daily value of vitamin C in a dose of ibuprofen, a functional relationship between the labeling and the vitamin C in a dose of ibuprofen, monitoring vitamin C consumed with ibuprofen, or regulating it. They teach away from the claimed method by not enabling it, its steps, or its desired results. So, Yeh et al, SS Pharmaceutical, Tsunoda and Krause do not disclose, inherently provide, or enable the claimed method, its steps, or its desired results. And, they teach away by not enabling the claimed method, its steps, or its desired results. Thus, *prima facie* obviousness of the invention is not established, since all of the features of the claimed invention are not shown by Yeh et al, SS Pharmaceutical, Tsunoda and Krause, which teach away from it, In re Royka, and Tec Air. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause, which does not establish *prima facie* obviousness.

FAILURE OF OTHERS TO FIND A SOLUTION OR MAKE THE INVENTION

The Court stated that objective criteria of patentability must always be considered, citing Graham v John Deere Co. 383 US 1, 17-18 (1966), Knoll Pharmaceutical v Teva Pharmaceuticals, 367 F3d 1381, 1385; 70 USPQ2d 1957 (Fed Cir 2004). The objective criteria include failure of others to find a solution to the problem, Pro-Mold & Tool Co v Great Lakes Plastics, Inc. 75 F3d 1568, 1572 (Fed Cir 1996). And, they include failure of others to make the invention, Transmatic, Inc v Gulton Indus., Inc. 53 F3d 1270, 1275 (Fed Cir 1995).

Ibuprofen has been used since 1969, see Attachment E. For decades others have failed to make the invention, which monitors vitamin C consumption and enables the consumer to regulate vitamin C consumption while consuming ibuprofen pain reliever with material that may include vitamin C. So, the claimed method has objective criteria for patentability in the failure of others to find a solution to the problem of not being able to monitor or regulate vitamin C consumption from consuming ibuprofen pain reliever, which may contain vitamin C, or make the invention of the claimed method. Thus, the claimed method has objective criteria of patentability, which must always be considered, Knoll Pharmaceutical. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause, since they and others failed to find a solution to the problem of not being able to monitor or regulate vitamin C consumed from consuming ibuprofen pain reliever, or make the claimed method.

Claimed Method, Its Steps, Product Used & Result Neither Disclosed By Art

[III] The elected claimed method of monitoring the consumption of vitamin C with ibuprofen, is not obvious, since neither the method nor its steps of a) labeling an amount and percent daily value of vitamin C in a dose of ibuprofen, b) consuming the dose from the labeled product, and c) monitoring the vitamin C consumed, are disclosed, inherently provided, or enabled by the prior art. Nor, does it disclose, inherently provide, or enable the desired result of the claimed method of regulating vitamin C consumption. The elected claimed method requires a product having labeling indicating the amount and percent daily value

of vitamin C in a dose of ibuprofen, and the steps of labeling an enclosure with labeling indicating the amount and percent daily value of the vitamin C in a dose of ibuprofen, consuming the dose from the labeled product, and monitoring the vitamin C consumed, and it produces the useful result of enabling the consumer to regulate consumption of the vitamin C, which are not disclosed by the prior art.

All of the features of the claimed invention must be shown to establish *prima facie* obviousness of the invention, *In re Royka*, 490 F2d 981, 180 USPQ 580 (CCPA 1974), MPEP 2143.3. Krause does not disclose ibuprofen or a discomfort reliever. Yeh et al, SS Pharmaceutical or Tsunoda teach vitamin C as an antioxidant percent of a pain reliever composition. They do not teach an amount or percent daily value of vitamin C to supplement nutrition. They do not teach the labeling or monitoring steps of the claimed invention, as stated by the Examiner, at page 5 of the official action dated July 23, 2007. They do not disclose, inherently provide, or enable the elected claimed method of monitoring the consumption of vitamin C with ibuprofen, or its steps of a) the labeling an amount and percent daily value of vitamin C in a dose of ibuprofen, which provides a functional relationship between labeling and vitamin C in a dose of ibuprofen, b) consuming the dose from the labeled product, and c) monitoring the vitamin C consumed with ibuprofen, as required by the elected claimed method. Nor, does the prior art of record disclose, inherently provide, or enable the desired result of the claimed method of regulating vitamin C consumption. So, the elected claimed method of monitoring the consumption of vitamin C with ibuprofen, is not obvious, since neither the method nor its steps of a) labeling an amount and percent daily value of vitamin C in a dose of ibuprofen, b) consuming the dose from the labeled product, and c) monitoring the vitamin C consumed, are disclosed, inherently provided, or enabled by the prior art of record. Nor, does it disclose, inherently provide, or enable the desired result of the claimed method of regulating vitamin C consumption. Thus, *prima facie* obviousness of the invention is not established since all of the features of the claimed invention are not shown by the prior art, *In re Royka*. Accordingly, the claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and

Krause.

A method consists of steps, NTP, Inc, v Research in Motion, Ltd 418 F.3d 1282, 1318, 1322 (CAFC 2005). A method is an act, or mode of acting. ... Either may be a means of producing a useful result. ... Providing certain substances together is a method, Tilghman v. Proctor, 102 US 707, 728 (1881). The elected claimed method requires a product having labeling indicating the amount and percent daily value of vitamin C in a dose of ibuprofen, and the steps of labeling an enclosure with labeling indicating the amount and percent daily value of the vitamin C in a dose of ibuprofen, consuming the dose from the labeled product, and monitoring the vitamin C consumed, and it produces the useful result of enabling the consumer to regulate consumption of the vitamin C, which are not disclosed by Yeh et al, SS Pharmaceutical, Tsunoda and Krause. Yeh et al, SS Pharmaceutical, Tsunoda and Krause do not disclose the steps of the claimed method, or produce the useful result of the elected claimed method of enabling the consumer to regulate consumption of the vitamin C. And, they do not disclose a product having labeling indications indicating the amount and percent daily value of vitamin C in a dose of ibuprofen, as provided by the labeling step of the elected claimed method. So, the elected claimed method requires a product having labeling indicating the amount and percent daily value of vitamin C in a dose of ibuprofen, and the steps of labeling an enclosure with labeling indications indicating the amount and percent daily value of the vitamin C in a dose of ibuprofen, consuming the dose, and monitoring the vitamin C consumed, and it produces the useful result of enabling the consumer to regulate consumption of the vitamin C, which are not disclosed by Yeh et al, SS Pharmaceutical, Tsunoda and Krause. Thus, the prior art does not disclose the elected claimed method, since it does not disclose the product used by the method, or the steps of the method, NTP, Inc, v Research in Motion and Tilghman v. Proctor. Accordingly, the claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause.

Yeh et al Do Not Disclose Amount Of Vitamin C

[IV] Yeh et al do not disclose an amount of vitamin C, or a product having

labeling indicating the amount and percent daily value of vitamin C in a dose of ibuprofen, as required by the elected claimed method. And, Yeh et al do not disclose steps of the elected claimed method of labeling the amount and percent daily value of vitamin C in a dose of ibuprofen, consuming the dose from the labeled product, or monitoring the amount of vitamin C consumed. Yeh et al disclose a composition having a percent of antioxidant and a percent of ibuprofen, (see column 4, lines 7-10). The prior art neither inherently provides, teaches, nor discloses labeling an amount and percent daily value of vitamin C in a dose of ibuprofen, a functional relationship between labeling and vitamin C in the dose of ibuprofen, consuming the dose from the product labeled, enabling monitoring vitamin C consumed or monitoring vitamin C consumed, as provided by the elected claimed method. Therefore, the prior art teaches away by neither monitoring vitamin C consumed, nor enabling it (2) leading in a direction divergent from of path taken by Applicant in the elected claimed method by labeling the amount and percent daily value of vitamin C in a dose of ibuprofen, which provides a functional relationship between labeling and vitamin C in the dose, that enables monitoring the amount of vitamin C consumed. And, by not enabling monitoring consumption of vitamin C, Yeh et al suggest a line of development that is unlikely to produce the (3) results sought by Applicant, of enabling the consumer to regulate consumption of vitamin C, since the consumer cannot regulate consumption of vitamin C without monitoring it, and Yeh et al do not enable monitoring it.

All of the features of the claimed invention must be shown to establish prima facie obviousness of the invention, In re Royka, 490 F2d 981, 180 USPQ 580 (CCPA 1974), MPEP 2143.3. Yeh et al teach vitamin C antioxidant as a percent of a composition. Yeh et al do not disclose labeling an amount or percent daily value of vitamin C in a dose of ibuprofen, or monitoring its consumption as required by the claimed method. And, Yeh et al do not disclose a product having labeling indicating the amount and percent daily value of vitamin C in a dose of ibuprofen, as required by the labeling and monitoring steps of the claimed method. So, Yeh et al do not disclose a product having labeling

indicating the amount and percent daily value of vitamin C in a dose of ibuprofen, as required by the elected claimed method. And, Yeh et al do not disclose steps of the claimed method of labeling the amount and percent daily value of vitamin C in a dose of ibuprofen, consuming the dose from the labeled product, or monitoring the amount of vitamin C consumed. Thus, *prima facie* obviousness of the invention is not established since all of the features of the claimed invention are not shown by the prior art, In re Royka. Accordingly, the claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause.

There is no teaching to establish a *prima facie* case of obviousness, if a reference teaches away from (2) a path taken or (3) a result sought by the applicant, Tec Air. Yeh et al do not disclose a product having labeling indications indicating the amount and percent daily value of vitamin C, as provided by the labeling step, and used by the consuming, and monitoring steps of the claimed method. Yeh et al (and SS Pharmaceutical and Tsunoda) do not disclose a functional relationship between any vitamin C in a dose and labeling, or labeling an amount and percent daily value of vitamin C, or monitoring vitamin C consumption, as required by all of the claims. So, the prior art of record neither inherently provides, teaches, nor discloses labeling an amount and percent daily value of vitamin C in a dose of ibuprofen, a functional relationship between labeling and vitamin C in the dose of ibuprofen, consuming the dose from the product labeled, enabling monitoring vitamin C consumed or monitoring vitamin C consumed, as provided by the elected claimed method. Therefore, Yeh et al (and SS Pharmaceutical and Tsunoda) teach away by neither monitoring vitamin C consumed, nor enabling it (2) leading in a direction divergent from of path taken by Applicant in the elected claimed method by labeling the amount and percent daily value of vitamin C in a dose of ibuprofen, which provides a functional relationship between labeling and vitamin C in the dose, that enables monitoring the amount of vitamin C consumed. And, by not enabling monitoring consumption of vitamin C, Yeh et al suggest a line of development that is unlikely to produce the (3) results sought by Applicant, of

enabling the consumer to regulate consumption of vitamin C, since the consumer cannot regulate consumption of vitamin C without monitoring it, and Yeh et al do not enable monitoring it. Thus, there is no teaching to establish a prima facie case of obviousness, since Yeh et al teach away from (2) a path taken or (3) a result sought by Applicant, Tec Air. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause since they do not establish a prima facie case of obviousness.

One Cannot Use Hindsight To Pick And Choose Among Isolated Disclosures

[V] While Krause teaches well known information about food labeling, Krause does not disclose ibuprofen (or a discomfort reliever) or teach a method of monitoring vitamin C consumed with ibuprofen, or any of the steps of the claimed method of a) labeling the amount and percent daily value of vitamin C in a dose of ibuprofen, which provides a functional relationship with vitamin C in the dose, that enables monitoring vitamin C consumption, b) consuming the dose from the product labeled, and c) monitoring the amount of vitamin C consumed. And, rejection of the claims in view of Krause imbues one of ordinary skill in the art with knowledge of a product having labeling, which is functionally related to an amount of vitamin C in a dose of ibuprofen, and used in a method for monitoring consumption of vitamin C in the dose. Yet, neither Krause nor any other prior art reference of record conveys or suggests that knowledge, and the rejection has fallen victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against the teacher. It uses the inventor's patent specification teaching of both a novel and unobvious invention as though it were prior art in order to make claims appear to be obvious by combining without any teaching in the references to combine them. The prior art of record does not disclose a method of monitoring vitamin C consumed with ibuprofen, or a product having labeling, which is functionally related to the amount of vitamin C in a dose of ibuprofen, as provided by the elected claimed method.

To imbue one of ordinary skill in the art with knowledge of the invention when no prior art reference of record conveys or suggests that knowledge is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the

inventor taught is used against the teacher, In re Fine, 837 F2d 1071, 1075, 5 USPQ 2d 1598, 1600 (Fed. Cir. 1988). One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention, In re Fine at 1600. Whether a particular combination of references might be obvious to try is not a legitimate test for patentability, In re Fine at 1599. Krause discloses labeling food. Krause does not disclose ibuprofen, or ibuprofen with vitamin C. Yeh et al, SS Pharmaceutical and Tsunoda do not disclose an ibuprofen product having labeling indications indicating an amount or percent daily value of vitamin C, or a method for monitoring consumption of vitamin C with ibuprofen from an enclosure having labeling indications of the amount and percent daily value of vitamin C, or labeling the amount and percent daily value of vitamin C in a dose of ibuprofen, consuming the dose of ibuprofen from the labeled product indicating the amount and percent daily value of vitamin C, or monitoring vitamin C consumption, or a functional relationship between any vitamin C in a dose and labeling. So, while Krause teaches well known information about food labeling, Krause does not teach a method of monitoring vitamin C consumed with ibuprofen, or any of the steps of the claimed method of a) labeling the amount and percent daily value of vitamin C in a dose of ibuprofen, which provides a functional relationship with vitamin C in the dose, that enables monitoring vitamin C consumption, b) consuming the dose from the product labeled, and c) monitoring the amount of vitamin C consumed. And, the rejection in view of Krause imbues one of ordinary skill in the art with knowledge of a product having labeling, which is functionally related to an amount of vitamin C in a dose of ibuprofen, and used in a method for monitoring consumption of vitamin C in the dose. Yet, neither Krause nor any other prior art reference of record conveys or suggests that knowledge, and the rejection has fallen victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against the teacher. Thus, the obviousness rejection is a prohibited use of hindsight reconstruction, since it picks and chooses among isolated disclosures to select the features required to carry out the elected claimed method, when no prior art reference of record conveys or suggests that knowledge In re

Fine. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause, as such is a prohibited use of hindsight reconstruction.

It is legal error to use the inventor's patent specification teaching of both a novel and unobvious invention as though it were prior art in order to make claims appear to be obvious In re Pleuddemann, 901 F2d 823, 828, 15 USPQ 2d 1738, 1742 (Fed. Cir 1990). Krause does not disclose ibuprofen or a discomfort reliever. Yeh et al, SS Pharmaceutical and Tsunoda do not disclose an ibuprofen product having labeling indicating an amount and percent daily value of vitamin C, or a method for monitoring consumption of vitamin C with ibuprofen from an enclosure with labeling of the amount and percent daily value of vitamin C in a dose of ibuprofen, or monitoring vitamin C consumed with a dose of ibuprofen, or a functional relationship between labeling and vitamin C in a dose of ibuprofen. So, constructing the rejection uses the inventor's patent specification teaching of both a novel and unobvious invention as though it were prior art in order to make claims appear to be obvious by combining Yeh et al, SS Pharmaceutical and Tsunoda without any teaching in the references to combine them. They do not disclose a method of monitoring vitamin C consumed with ibuprofen, or a product having labeling, which is functionally related to the amount of vitamin C in a dose of ibuprofen, as provided by the elected claimed method. Thus, the combination is legal error, since it uses the inventor's patent specification teaching of both a novel and unobvious invention as though it were prior art, In re Pleuddemann. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause, as such is legal error.

Multiple Use Pain Reliever And Nutritional Supplement Not Known

[VI] [1] While Krause teaches food labeling, Krause does not disclose a dosage form for ibuprofen pain reliever and vitamin C nutritional supplement, or labeling a product for a dose of ibuprofen pain reliever and vitamin C nutritional supplement, or labeling which is functionally related to the amount of vitamin C in a dose of ibuprofen, or a method for monitoring vitamin C consumed in a dose of ibuprofen, or monitoring vitamin C consumption with ibuprofen, as provided by

the elected claimed method. And, while Krause discloses food labeling, Krause (and Yeh et al) does not provide consumers and their administrators with a teaching which enables them to monitor or regulate consumption of vitamin C, or a container with labeling indicating the amount and percent daily value of vitamin C in a unit dose of ibuprofen, which enables monitoring consumption of vitamin C, as provided by the elected claimed method. Also, Krause does not provide consumers and their administrators with a teaching of a multiple use dosage form of ibuprofen pain reliever and vitamin C nutritional supplement, or a multiple use dosage form product of ibuprofen pain reliever and vitamin C nutritional supplement having labeling indicating an amount and percent daily value of vitamin C, which enables monitoring consumption of vitamin C while consuming ibuprofen, as provided by the elected claimed method. [2] The prior art of record discloses a dose having ibuprofen, but neither inherently provides, teaches, nor discloses a step or a functional relationship needed to enable monitoring vitamin C consumed with ibuprofen, or monitoring vitamin C consumed with ibuprofen, as provided by the elected claimed method. And, it neither inherently provides, teaches, nor discloses a) labeling an amount and percent daily value of vitamin C in a dose of ibuprofen, b) a functional relationship between labeling and vitamin C in the dose of ibuprofen, c) a product having a dose of ibuprofen and labeling of the amount and percent daily value of vitamin C in the dose, or d) consuming the dose from the labeled product, as provided by the elected claimed method. Therefore, Krause and the prior art of record teach away by neither monitoring nor enabling monitoring vitamin C consumption, (2) leading in a direction divergent from of path taken by Applicant in the claimed method of monitoring vitamin C consumption by labeling the amount and percent daily value of vitamin C in a dose of ibuprofen, which provides a functional relationship between labeling and vitamin C in the dose, and enables monitoring and regulation of consumption of the vitamin C, while consuming the dose of ibuprofen. Consequently, Krause and the prior art of record teach away leading in a direction divergent from (2) the path that was taken and (3) a result sought by (A) the claimed method of monitoring consumption of vitamin C with ibuprofen, (B)

the product required by the claimed method having labeling indicating the amount and percent daily value of vitamin C in a dose of ibuprofen, (C) the step of the claimed method of labeling the amount of the vitamin C in a dose of ibuprofen, (D) the step of the elected claimed method of consuming the dose from the labeled enclosure, (E) the step of the elected claimed method of monitoring the vitamin C consumed, and (F) the result of the elected claimed method of enabling regulation of consumption of vitamin C, while consuming the dose of ibuprofen. [3] The claimed method for monitoring consumption of vitamin C with ibuprofen by labeling a product with the amount and percent daily value of vitamin C in a dose of ibuprofen, consuming the dose from the labeled product, and monitoring the vitamin C consumed, is not obvious since: i) the elected claimed method and the steps of the elected claimed method and the functional relationship needed by the elected claimed method are not disclosed in the prior art of record, ii) the prior art of record teaches away from the elected claimed method and its desired results, and iii) the elected claimed method satisfies a long felt need. The labeling and its functional relationship to the vitamin C in the dose of ibuprofen are new and unobvious making the elected claimed method of monitoring consumption of vitamin C in a dose of ibuprofen patentable. Consequently, it follows that the elected claimed method of monitoring consumption of vitamin C using the product labeled to indicate the amount and percent daily value of vitamin C in a dose of ibuprofen is not obvious, especially in view of Krause, which discloses food labeling, but does not disclose labeling the amount or percent daily value of vitamin C in a dose of ibuprofen, or a functional relationship between labeling and and vitamin C in a dose of ibuprofen, or monitoring vitamin C consumed with the dose of ibuprofen. And, the claimed method is not obvious, since it cures defects of an ibuprofen product in use for decades. The step of the claimed method of labeling indicating the amount and percent daily value of vitamin C in a dose of ibuprofen provides a nonobvious functional relationship to the vitamin C in the dose, which enables monitoring vitamin C consumption, and cures defects of a product in use for decades. The

claimed method produces the desired result of enabling consumers to regulate their consumption of vitamin C.

[1] All of the features of the claimed invention must be shown to establish *prima facie* obviousness of the invention, *In re Royka*, 490 F2d 981, 180 USPQ 580 (CCPA 1974), MPEP 2143.3. Krause discloses food labeling. Krause does not disclose or provide a labeled product for a dose of ibuprofen pain reliever and vitamin C nutritional supplement, or indicating an amount or percent daily value of vitamin C in a dose of ibuprofen, or monitoring consumption of vitamin C consumed with ibuprofen, or a functional relationship between labeling and vitamin C in a dose of ibuprofen, or an ibuprofen product having labeling indicating an amount or percent daily value of vitamin C, or a method for monitoring consumption of vitamin C with ibuprofen from an enclosure having labeling enabling monitoring of consumption of vitamin C, as provided by the elected claimed method. So, Krause does not disclose a dosage form for ibuprofen pain reliever and vitamin C nutritional supplement, or labeling a product for a dose of ibuprofen pain reliever and vitamin C nutritional supplement, or labeling which is functionally related to vitamin C in a dose of ibuprofen, or a method for monitoring vitamin C consumed in a dose of ibuprofen, or monitoring vitamin C consumed with ibuprofen, as provided by the elected claimed method. And, Krause (and Yeh et al) does not provide consumers and their administrators with a teaching which enables them to monitor or regulate consumption of vitamin C with ibuprofen, or a container with labeling indicating the amount and percent daily value of vitamin C in a unit dose of ibuprofen, which enables monitoring consumption of vitamin C with ibuprofen, as provided by the elected claimed method. Also, Krause does not provide consumers and their administrators with a teaching of a multiple use dosage form of ibuprofen pain reliever and vitamin C nutritional supplement, or a multiple use dosage form product of ibuprofen pain reliever and vitamin C nutritional supplement having labeling indicating an amount and percent daily value of vitamin C, which enables monitoring consumption of vitamin C while consuming ibuprofen, as provided by the elected claimed method. Thus, *prima facie* obviousness of the claimed invention is not

established, since all of the claim limitations are not taught or suggested by the prior art of record, In re Royka, MPEP 2143.3. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause, as they do not establish *prima facie* obviousness of the claimed invention.

[2] There is no teaching to establish a *prima facie* case of obviousness, if a reference teaches away from (2) a path taken or (3) a result sought by the applicant, Tec Air. Krause does not disclose ibuprofen. Krause (and prior art of record) does not disclose labeling indications indicating the amount or percent daily value of vitamin C (or any other nutritional supplement) in a unit dose of ibuprofen and vitamin C, or an ibuprofen product having labeling indications indicating an amount and percent daily value of vitamin C in a dose of ibuprofen, or monitoring vitamin C consumption with ibuprofen, or a functional relationship between labeling and vitamin C in a dose of ibuprofen. By not disclosing or enabling monitoring vitamin C consumed with ibuprofen, or labeling indicating an amount and percent daily value of vitamin C in a unit dose of ibuprofen and vitamin C, or an ibuprofen product having labeling indicating an amount and percent daily value of vitamin C, or a functional relationship between labeling and vitamin C in a dose of ibuprofen, Krause teaches (A) away from the claimed method of monitoring consumption of vitamin C with ibuprofen, (B) away from the product required by the claimed method having labeling indicating the amount and percent daily value of vitamin C in a dose of ibuprofen, (C) away from the step of the claimed method of labeling the amount ad percent daily value of the vitamin C in a dose of ibuprofen, (D) away from the step of the claimed method of consuming the dose from the labeled enclosure, (E) away from the step of the claimed method of monitoring the vitamin C consumed, and (F) away from the result of the claimed method of enabling the consumer to regulate consumption of vitamin C, while consuming the dose of ibuprofen. So, Krause (and the prior art of record) neither inherently provides, teaches, nor discloses a step or a functional relationship needed to enable monitoring vitamin C consumed with ibuprofen, or monitoring vitamin C consumed with ibuprofen, as provided by the

elected claimed method. And, it neither inherently provides, teaches, nor discloses a) labeling an amount and percent daily value of vitamin C in a dose of ibuprofen, b) a functional relationship between labeling and vitamin C in the dose of ibuprofen, c) a product having a dose of ibuprofen and labeling of the amount and percent daily value of vitamin C in the dose, or d) consuming the dose from the labeled product, as provided by the elected claimed method. Therefore, Krause teaches away by neither monitoring nor enabling monitoring vitamin C consumption, (2) leading in a direction divergent from of path taken by Applicant in the elected claimed method of monitoring vitamin C consumption by labeling the amount and percent daily value of vitamin C in a dose of ibuprofen, which provides a functional relationship between labeling and vitamin C in the dose, and enables monitoring and regulation of consumption of the vitamin C, while consuming the dose of ibuprofen. Consequently, Krause teaches away leading in a direction divergent from (2) the path that was taken and (3) a result sought by (A) the elected claimed method of monitoring consumption of vitamin C with ibuprofen, (B) the product required by the elected claimed method having labeling indicating the amount of vitamin C in a dose of ibuprofen, (C) the step of the elected claimed method of labeling the amount and percent daily value of the vitamin C in a dose of ibuprofen, (D) the step of the elected claimed method of consuming the dose from the labeled enclosure, (E) the step of the elected claimed method of monitoring the vitamin C consumed, and (F) the result of the claimed method of enabling regulation of consumption of vitamin C, while consuming the dose of ibuprofen. Thus, there is no teaching to establish a prima facie case of obviousness, since Krause teaches away from (2) a path taken and (3) a result sought by Applicant, Tec Air. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause, since they do not establish a prima facie case of obviousness.

[3] i) All of the features of the claimed invention must be shown to establish prima facie obviousness of the invention, In re Royka, 490 F2d 981, 180 USPQ 580 (CCPA 1974), MPEP 2143.3. And, for printed matter and substrate the question is whether there exists any new and unobvious functional

relationship between them, In re Miller 164 USPQ 46, 49 (CCPA 1969), In re Gulack 217 USPQ 401, 404 (CAFC 1983) and In re Ngai at 1864. Krause teaches food labeling. However, Krause does not disclose dosage forms having ibuprofen and vitamin C, or an ibuprofen product having labeling indications indicating an amount or percent daily value of vitamin C. And, Krause, Yeh et al, and the prior art of record do not disclose a method of monitoring vitamin C consumed with ibuprofen, the step of the elected claimed method of labeling the amount and percent daily value of vitamin C in a dose of ibuprofen, a functional relationship between labeling and vitamin C in a dose of ibuprofen, which is needed for monitoring vitamin C consumption, or the step of the elected claimed method of monitoring vitamin C consumed with ibuprofen. In the elected claimed method labeling the amount and percent daily value of vitamin C would not achieve its monitoring, regulating purposes without the corresponding vitamin C in the dose of ibuprofen provided in the enclosure having the labeling indications. And, the dose of vitamin C with ibuprofen provided without labeling the amount and percent daily value of vitamin C in the dose would similarly be unable to produce the desired result of enabling consumers to regulate their consumption of vitamin C with ibuprofen. Therefore, the elected claimed method for monitoring consumption of vitamin C with ibuprofen by labeling a product with the amount and percent daily value of vitamin C in a dose of ibuprofen, consuming the dose from the labeled product, and monitoring the vitamin C consumed, is not obvious since: i) the elected claimed method and the steps of the elected claimed method and the functional relationship needed by the claimed method are not disclosed in the prior art of record.

ii) There is no teaching to establish a prima facie case of obviousness, if a reference teaches away from (2) a path taken or (3) a result sought by the applicant, Tec Air. Yeh et al, Krause and the prior art of record do not disclose labeling an amount of vitamin C in a dose of ibuprofen, or a functional relationship between labeling and vitamin C in a dose of ibuprofen needed to monitor vitamin C consumption, or consuming the dose of ibuprofen from the labeled product and monitoring vitamin C consumed, as required by the elected

claimed method. Yeh et al, and the prior art of record teach away (2) leading in a direction divergent from of path taken by Applicant, by disclosing a dose having ibuprofen, but without either inherently providing, teaching, or disclosing a) monitoring vitamin C consumed with ibuprofen, as provided by the elected claimed method or b) labeling an amount and percent daily value of vitamin C in a dose of ibuprofen, or c) a functional relationship between labeling and vitamin C in the dose of ibuprofen, which are needed for monitoring consumption of vitamin C in a dose of ibuprofen. Also, this teaches away suggesting a line of development that is unlikely to produce the (3) results sought by Applicant, of enabling the consumer to regulate consumption of vitamin C, by a method for monitoring consumption of vitamin C with ibuprofen from an enclosure having labeling, which is functionally related to the vitamin C in the dose of ibuprofen. Therefore, the elected claimed method for monitoring consumption of vitamin C with ibuprofen by labeling a product with the amount and percent daily value of vitamin C in a dose of ibuprofen, consuming the dose from the labeled product, and monitoring the vitamin C consumed, is not obvious since: ii) the prior art of record teaches away from the elected claimed method and its desired results.

iii) And, in holding an invention to be patentable the Court stated that during a period of half a century of use of a product no one devised a method of curing its defects, Goodyear Tire & Rubber Co. v Ray-O-Vac Co. 321 US 275 (1944). Similarly, during a period of decades of use of ibuprofen products no one devised a method of curing the defects. These defects result in its consumers' inability to monitor or regulate consumption of the vitamin C with ibuprofen. So, after decades of inability to monitor or regulate consumption of the vitamin C with ibuprofen, the elected claimed method monitors vitamin C consumption and enables consumers to regulate it by consuming a unit dose of ibuprofen pain reliever and vitamin C nutritional supplement from an enclosure having labeling indicating the amount and percent daily value of vitamin C. Therefore, the elected claimed method for monitoring consumption of vitamin C with ibuprofen by labeling a product with the amount and percent daily value of vitamin C in a dose of ibuprofen, consuming the dose from the labeled product, and monitoring the

vitamin C consumed, is not obvious since: iii) the elected claimed method satisfies a long felt need.

So, the elected claimed method for monitoring consumption of vitamin C with ibuprofen by labeling a product with the amount and percent daily value of vitamin C in a dose of ibuprofen, consuming the dose from the labeled product, and monitoring the vitamin C consumed, is not obvious since: i) the elected claimed method and the steps of the elected claimed method and the functional relationship needed by the elected claimed method are not disclosed in the prior art of record, ii) the prior art of record teaches away from the claimed method and its desired results, iii) the claimed method satisfies a long felt need. The labeling and its functional relationship to the vitamin C in the dose of ibuprofen are new and unobvious making the claimed method of monitoring consumption of vitamin C in a dose of ibuprofen patentable. Consequently, it follows that the claimed method of monitoring consumption of vitamin C using the product labeled to indicate the amount and percent daily value of vitamin C in a dose of ibuprofen is not obvious, especially in view of Krause, which discloses food labeling, but does not disclose labeling the amount or percent daily value of vitamin C in a dose of ibuprofen, or a functional relationship between labeling and vitamin C in a dose of ibuprofen, or monitoring vitamin C consumed with the dose of ibuprofen. And, the elected claimed method is not obvious, since it cures defects of an ibuprofen product in use for decades. The step of the elected claimed method of labeling indicating the amount and percent daily value of vitamin C in a dose of ibuprofen provides a nonobvious functional relationship to the vitamin C in the dose, which enables monitoring vitamin C consumption, and cures defects of a product in use for decades. The claimed method produces the desired result of enabling consumers to regulate their consumption of vitamin C. Thus, the claimed method provides a new and unobvious functional relationship that is not disclosed by the prior art of record, which teaches away from it, the elected claimed method cures defects of a product in use for decades, which are supportive of patentability, In re Royka, In re Ngai, Gulack, In re Miller, Tec Air and Goodyear Tire & Rubber Co. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS

Pharmaceutical, Tsunoda and Krause, since they do not disclose the new and unobvious functional relationship, which is supportive of patentability, and it does not cure defects in use for decades cured by the claimed method.

Administering Yeh et al Does Not Provide Claimed Method, But Teaches Away From It

[VII] It would not be obvious to one of ordinary skill in the art at the time of the invention to monitor vitamin C consumed in a dose of ibuprofen, as provided by the elected claimed method, while administering the ibuprofen composition of Yeh et al for treating pain, since they do not disclose monitoring consumption of vitamin C, or enable it. They do not disclose labeling indicating an amount of vitamin C in a dose of ibuprofen, or a functional relationship between labeling and vitamin C in a dose of ibuprofen, which are needed for monitoring consumption of vitamin C. Administering the ibuprofen composition of Yeh et al for treating pain does not provide, teach or suggest a) a method of monitoring consumption of vitamin C with ibuprofen, as provided by the elected claimed method, b) an ibuprofen product having labeling indicating an amount and percent daily value of vitamin C, which is needed to enable monitoring vitamin C consumption, c) the labeling, consuming or monitoring steps of the elected claimed method, or d) the result of the elected claimed method of enabling the consumer to regulate consumption of vitamin C, while consuming the dose of ibuprofen. Monitoring vitamin C consumption, as provided by the elected claimed method, would not be obvious to one of ordinary skill in the art at the time of the invention, by administering the ibuprofen composition of Yeh et al for treating pain, since the prior art of record discloses a dose of ibuprofen, but it does not disclose labeling an amount and percent daily value of vitamin C in a dose of ibuprofen, or a functional relationship between labeling and vitamin C in a dose of ibuprofen, which are needed to monitor vitamin C consumption. Yeh et al do not disclose or enable monitoring vitamin C consumed with ibuprofen by disclosing a dose of ibuprofen, since they do not disclose a) monitoring consumption of vitamin C, or b) labeling an amount or percent daily value of vitamin C in a dose of ibuprofen, or c) a functional relationship between the labeling and vitamin C in the dose, which are needed for monitoring consumption

of vitamin C in a dose of ibuprofen. Consequently, they teach away suggesting a line of development that is unlikely to produce the (3) results sought by Applicant, of enabling the consumer to regulate consumption of vitamin C, by a method for monitoring consumption of vitamin C in a dose of ibuprofen from an enclosure having labeling, which is functionally related to the vitamin C in the dose of ibuprofen.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art, *In re Royka*, 490 F2d 981, 180 USPQ 580 (CCPA 1974), MPEP 2143.3. Yeh et al, (and Krause and the prior art of record) do not disclose (A) a method for monitoring consumption of vitamin C with ibuprofen, or the elected claimed method for monitoring consumption of vitamin C with ibuprofen from an enclosure having labeling indications enabling monitoring of vitamin C consumption, (B) labeling indicating an amount and percent daily value of vitamin C in a dose of ibuprofen, or the ibuprofen product having labeling indications indicating an amount and percent daily value of vitamin C, which is needed to enable monitoring vitamin C consumption, (C) the step of the claimed method of labeling the amount and percent daily value of the vitamin C in a dose of ibuprofen, (D) the step of the claimed method of consuming a unit dose of ibuprofen from an enclosure having labeling enabling monitoring of consumption of vitamin C, (E) the step of the claimed method of monitoring consumption of vitamin C with ibuprofen, and (F) regulating consumption of vitamin C with ibuprofen, or the result of the elected claimed method of enabling the consumer to regulate consumption of vitamin C, while consuming the dose of ibuprofen. So, it would not be obvious to one of ordinary skill in the art at the time of the invention to monitor vitamin C consumed in a dose of ibuprofen, as provided by the elected claimed method, while administering the ibuprofen composition of Yeh et al for treating pain, since they do not disclose monitoring consumption of vitamin C, or enable it. They do not disclose labeling indicating an amount or percent daily value of vitamin C in a dose of ibuprofen, or a functional relationship between labeling and vitamin C in a dose of ibuprofen, which are needed for monitoring consumption of vitamin C.

Administering the ibuprofen composition of Yeh et al for treating pain does not provide, teach or suggest a) a method of monitoring consumption of vitamin C with ibuprofen, as provided by the elected claimed method, b) an ibuprofen product having labeling indicating an amount and percent daily value of vitamin C, which is needed to enable monitoring vitamin C consumption, c) the labeling, consuming or monitoring steps of the elected claimed method, or d) the result of the elected claimed method of enabling the consumer to regulate consumption of vitamin C, while consuming the dose of ibuprofen. Thus, *prima facie* obviousness of the elected claimed invention is not established, since all of the claim limitations are not taught or suggested by the prior art, *In re Royka*, MPEP 2143.3. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause as *prima facie* obviousness is not established.

There is no teaching to establish a *prima facie* case of obviousness, if a reference teaches away from (2) a path taken or (3) a result sought by the applicant, Tec Air. Yeh et al do not disclose labeling an amount or percent daily value of vitamin C, or a functional relationship between any vitamin C in a dose and labeling provided by the elected claimed method, or the ibuprofen product required by the elected claimed method having labeling indications indicating an amount and percent daily value of vitamin C in a dose of ibuprofen, or steps of labeling, consuming and monitoring vitamin C in a dose of ibuprofen, as required by the elected claimed method. So, monitoring vitamin C consumption, as provided by the elected claimed method, would not be obvious to one of ordinary skill in the art at the time of the invention, by administering the ibuprofen composition of Yeh et al for treating pain, since the prior art of record does not disclose labeling an amount and percent daily value of vitamin C in a dose of ibuprofen, or a functional relationship between labeling and vitamin C in a dose of ibuprofen, which are needed to monitor vitamin C consumption. Yeh et al teach away (2) leading in a direction divergent from of path taken by Applicant, by disclosing a dose having ibuprofen, but without either inherently providing, teaching, or disclosing a) monitoring vitamin C consumed with ibuprofen or

enabling it, as are provided by the elected claimed method or b) labeling an amount and percent daily value of vitamin C in a dose of ibuprofen, or c) a functional relationship between labeling and vitamin C in the dose of ibuprofen, which are needed for monitoring consumption of vitamin C in a dose of ibuprofen. Yeh et al do not disclose or enable monitoring vitamin C consumed with ibuprofen by disclosing a dose having ibuprofen, since they do not disclose a) monitoring consumption of vitamin C, or b) labeling an amount and percent daily value of vitamin C in a dose of ibuprofen, or c) a functional relationship between the labeling and vitamin C in the dose, which are needed for monitoring consumption of vitamin C in a dose of ibuprofen. Consequently, they teach away suggesting a line of development that is unlikely to produce the (3) results sought by Applicant, of enabling the consumer to regulate consumption of vitamin C, by a method for monitoring consumption of vitamin C in a dose of ibuprofen from an enclosure having labeling, which is functionally related to the amount of vitamin C in the dose of ibuprofen. Thus, there is no teaching to establish a prima facie case of obviousness, since Yeh et al teach away from (2) a path taken or (3) a result sought by Applicant, Tec Air. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause as a prima facie case of obviousness is not established.

Commercial Ibuprofen Labeling Does Not Indicate Any % Daily Value or Amount of Antioxidant, Vitamin C or Nutritional Supplement

VIII Labeling of commercial ibuprofen does not indicate any percent daily value or amount of antioxidant, vitamin C or nutritional supplement. Monitoring vitamin C consumption, as provided by the elected claimed method, would not be obvious to one of ordinary skill in the art at the time of the invention, by administering the ibuprofen composition of the ibuprofen prior art of record or commercially available ibuprofen products for treating pain (Attachments B and C), since they do not disclose labeling an amount of vitamin C in a dose of ibuprofen, or a functional relationship between labeling and vitamin C in a dose of ibuprofen, which are needed to monitor vitamin C consumption.

There is no teaching to establish a prima facie case of obviousness, if a

reference teaches away from (2) a path taken or (3) a result sought by the applicant, Tec Air. Antioxidants added to ibuprofen do not need to be nutritional supplements, see US Patent 5185373 column 2, lines 25-53, see Attachment A. Some commercially available ibuprofen (Motrin) does not include an antioxidant, see Attachment B. The labeling does not indicate an amount for any ingredient, except ibuprofen. And, some commercially available ibuprofen (Advil) labeling lists (under inactive ingredients) sodium benzoate, which is a preservative and antioxidant, see Attachments C and D. However, the labeling does not indicate an amount for it or any other ingredient, except ibuprofen. And, the labeling does not indicate a percent daily value for antioxidant, or any other ingredient. Antioxidants added to ibuprofen do not need to be nutritional supplements (Attachment A). And, labeling for commercially available ibuprofen does not indicate an amount for an antioxidant, or any other ingredient, except ibuprofen, (Attachments B and C). Also, labeling for commercially available ibuprofen does not indicate a percent daily value for any ingredient, (Attachments B and C). Thus, labeling of commercial ibuprofen does not indicate any percent daily value or amount of antioxidant, vitamin C or nutritional supplement.

The ibuprofen prior art and commercially available ibuprofen do not disclose labeling (or label) an amount or percent daily value of vitamin C, or a functional relationship between any vitamin C in a dose and labeling provided by the elected claimed method, or the ibuprofen product required by the elected claimed method having labeling indications indicating an amount and percent daily value of vitamin C in a dose of ibuprofen, or steps of labeling, consuming and monitoring vitamin C in a dose of ibuprofen, as required by the elected claimed method. So, monitoring vitamin C consumption, as provided by the elected claimed method, would not be obvious to one of ordinary skill in the art at the time of the invention, by administering the ibuprofen composition of the ibuprofen prior art or commercially available ibuprofen for treating pain, since they do not disclose labeling an amount or percent daily value of vitamin C in a dose of ibuprofen, or a functional relationship between labeling and vitamin C in a dose of ibuprofen, which are needed to monitor vitamin C consumption. They

teach away (2) leading in a direction divergent from of path taken by Applicant, by disclosing a dose having ibuprofen, but without either inherently providing, teaching, or disclosing a) monitoring vitamin C consumed with ibuprofen or enabling it, as are provided by the elected claimed method or b) labeling an amount and percent daily value of vitamin C in a dose of ibuprofen, or c) a functional relationship between labeling and vitamin C in the dose of ibuprofen, which are needed for monitoring consumption of vitamin C in a dose of ibuprofen. They do not disclose or enable monitoring vitamin C consumed with ibuprofen by disclosing a dose having ibuprofen, since they do not disclose a) monitoring consumption of vitamin C, or b) labeling an amount or percent daily value of vitamin C in a dose of ibuprofen, or c) a functional relationship between the labeling and vitamin C in the dose, which are needed for monitoring consumption of vitamin C in a dose of ibuprofen. Consequently, they teach away suggesting a line of development that is unlikely to produce the (3) results sought by Applicant, of enabling the consumer to regulate consumption of vitamin C, by a method for monitoring consumption of vitamin C in a dose of ibuprofen from an enclosure having labeling, which is functionally related to the amount of vitamin C in the dose of ibuprofen. Thus, there is no teaching to establish a prima facie case of obviousness, since they teach away from (2) a path taken or (3) a result sought by Applicant, Tec Air. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause as a prima facie case of obviousness is not established.

Prior Art Does Not Employ Monitoring Vitamin C Consumed With Ibuprofen

[IX] A) It would not have been obvious to one of ordinary skill in the art to employ the monitoring step of the claimed method, since the prior art and, commercially available ibuprofen products (Attachments B and C) do not disclose 1) monitoring consumption of vitamin C (or any other nutritional supplement) with ibuprofen, or 2) labeling the amount or percent daily value of vitamin C (or any other nutritional supplement) in a dose of ibuprofen and 3) a functional relationship between the labeling and the vitamin C (or any other nutritional supplement) in a dose of ibuprofen, which are needed to enable monitoring

vitamin C consumed with ibuprofen.

B) A person of ordinary skill would be (1) discouraged from employing the monitoring step into the claimed method by following the path set out in Yeh et al, which neither inherently provides, teaches, nor discloses monitoring the amount of the vitamin C consumed in a dose of ibuprofen, or enable it by labeling the amount of the vitamin C in a dose of ibuprofen, and providing a functional relationship between labeling and vitamin C in the dose of ibuprofen.

C) The monitoring step of the claimed method and the functional relationship needed to carry it out are not disclosed by the prior art, which teaches away (A). A person of ordinary skill would be (1) discouraged from employing the monitoring step by following the path of the prior art, which neither inherently provides, teaches, discloses, nor enables it (B). The elected claimed method with its step of monitoring vitamin C consumption is enabled by the labeling step and the functional relationship between labeling and vitamin C in a dose of ibuprofen. Therefore, the elected claimed method with its step of monitoring vitamin C consumption is nonobvious and supportive of patentability, since it is not disclosed by the prior art, which teaches away from monitoring vitamin C consumption and it i) satisfies a long felt need, ii) solves the problem, which others have failed to solve of not being able to monitor and regulate vitamin C consumption from consuming ibuprofen pain reliever.

D) It would not have been obvious to one of ordinary skill in the prior art to employ the monitoring step into a method to produce the result sought by Applicant of regulating vitamin C consumption, since the prior art (3) suggests development without monitoring the amount or percent daily value of vitamin C consumed with a dose of ibuprofen, or labeling the amount or percent daily value of vitamin C in a dose of ibuprofen and providing a functional relationship between the labeling and the vitamin C in a dose of ibuprofen, which are needed for monitoring vitamin C consumption. And, without monitoring vitamin C consumption it is unlikely to produce the results sought by Applicant of regulating vitamin C consumption, since monitoring vitamin C consumption is needed to regulate it.

A) All of the features of the claimed invention must be shown to establish prima facie obviousness of the invention, In re Royka, 490 F2d 981, 180 USPQ 580 (CCPA 1974), MPEP 2143.3. Yeh et al do not disclose employing monitoring vitamin C, labeling products to enable monitoring consumption of vitamin C (or any other nutritional supplement), or a functional relationship between the labeling and the vitamin C in a dose of ibuprofen, or monitoring consumption of vitamin C with ibuprofen as required by the elected claimed method. And, Yeh et al do not teach the labeling or monitoring steps of the elected claimed invention, as stated by the Examiner, at page 5 of the official action dated July 23, 2007. Also, commercially available ibuprofen products (Attachments B and C) do not label the products to enable monitoring consumption of vitamin C (or any other nutritional supplement), to provide a functional relationship between the labeling and the vitamin C in a dose of ibuprofen, or to provide a method for monitoring consumption of vitamin C with ibuprofen, as provided by the elected claimed method. So, it would not have been obvious to one of ordinary skill in the art to employ the monitoring step of the elected claimed method, since the prior art of record and, commercially available ibuprofen products (Attachments B and C) do not disclose 1) monitoring consumption of vitamin C (or any other nutritional supplement) with ibuprofen, or 2) labeling the amount of vitamin C (or any other nutritional supplement) in a dose of ibuprofen and 3) a functional relationship between the labeling and the vitamin C (or any other nutritional supplement) in a dose of ibuprofen, which are needed to enable monitoring vitamin C consumed with ibuprofen. Thus, prima facie obviousness of the invention is not established since all of the features of the claimed invention are not shown by the prior art of record, In re Royka. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause.

B) The step of monitoring vitamin C consumption of the elected claimed method and the functional relationship needed to carry it out are not disclosed by the prior art of record, which teaches away from monitoring vitamin C consumption. And, for printed matter and substrate the question is whether

there exists any new and unobvious functional relationship between them, In re Miller 164 USPQ 46, 49 (CCPA 1969), In re Gulack 217 USPQ 401, 404 (CAFC 1983) and In re Ngai at 1864. In the elected claimed method labeling the amount of vitamin C would not achieve its monitoring, and regulating, purposes without the corresponding of vitamin C in the dose of ibuprofen provided in the enclosure having the labeling indications. And, the dose of vitamin C with ibuprofen provided without labeling indicating the amount and percent daily value of vitamin C in the dose would similarly be unable to produce the desired results of enabling consumers to monitor and regulate their consumption of vitamin C. Therefore, there exists a new and unobvious functional relationship between the labeling, and the vitamin C in the dose. And, this functional relationship produces the desired results of enabling consumers to monitor and regulate their consumption of vitamin C. A case of prima facie obviousness is not established, if a reference teaches away from the combination when a person of ordinary skill, upon reading the reference, would be (1) discouraged from following the path set out in the reference, Tec Air. The prior art of record discloses a dose having ibuprofen. But, it neither inherently provides, teaches, nor discloses monitoring the amount of the vitamin C consumed in a dose of ibuprofen, or enable it by labeling the amount and percent daily value of the vitamin C in a dose of ibuprofen, and providing a functional relationship between labeling and vitamin C in the dose of ibuprofen. So, a person of ordinary skill would be (1) discouraged from employing the monitoring step of the elected claimed method by following the path set out in Yeh et al, which neither inherently provides, teaches, nor discloses monitoring the amount of the vitamin C consumed in a dose of ibuprofen, or enable it by labeling the percent daily value of the vitamin C in a dose of ibuprofen, and providing a functional relationship between labeling and vitamin C in the dose of ibuprofen.

C) The monitoring step of the claimed method and the functional relationship needed to carry it out are not disclosed by the prior art of record, which teaches away (A). A person of ordinary skill would be (1) discouraged

from employing the monitoring step by following the path of the prior art of record, which neither inherently provides, teaches, discloses, nor enables it (B).

i) The claimed method with its step of monitoring vitamin C consumption satisfies a long felt need. In holding an invention to be patentable the Court stated that during a period of half a century of use of a product no one devised a method of curing its defects, Goodyear Tire & Rubber Co. v Ray-O-Vac Co. 321 US 275 (1944). Similarly, during decades of use of ibuprofen products no one devised a method of curing the defects. These defects result in its consumers' inability to monitor or regulate consumption of vitamin C. After decades of inability to monitor or regulate consumption of the vitamin C, the elected claimed method with its step of monitoring vitamin C consumption enables consumers to regulate it by consuming a unit dose of ibuprofen pain reliever and vitamin C nutritional supplement from an enclosure having labeling indicating the amount and percent daily value of vitamin C. The prior art of record discloses a product having a dose of ibuprofen, but it neither inherently provides, nor teaches, nor discloses labeling an amount or percent daily value of vitamin C in a dose of ibuprofen, or a functional relationship between labeling and vitamin C in the dose of ibuprofen, or monitoring vitamin C consumed with ibuprofen, as provided by the elected claimed method. Therefore, the elected claimed method with its step of monitoring vitamin C consumption satisfies a long felt need.

ii) The elected claimed method with its step of monitoring vitamin C consumption, solves the problem, which others have failed to solve of not being able to monitor or regulate vitamin C consumption from consuming ibuprofen pain reliever, or make the invention of the claimed method. The objective criteria include failure of others to find a solution to the problem, Pro-Mold & Tool Co v Great Lakes Plastics, Inc. 75 F3d 1568, 1572 (Fed Cir 1996). And, they include failure of others to make the invention, Transmatic, Inc v Gulton Indus., Inc. 53 F3d 1270, 1275 (Fed Cir 1995). The elected claimed method has objective criteria for patentability in the failure of others to find a solution to the problem of not being able to monitor or regulate vitamin C consumption from consuming ibuprofen pain reliever, which may contain vitamin C, or make the invention of the

elected claimed method. Therefore, the elected claimed method with its step of monitoring vitamin C consumption solves the problem, which others have failed to solve of not being able to monitor or regulate vitamin C consumption from consuming ibuprofen pain reliever, which may contain vitamin C, or make the invention of the claimed method.

So, the monitoring step of the elected claimed method and the functional relationship needed to carry it out are not disclosed by the prior art of record, which teaches away (A). A person of ordinary skill would be (1) discouraged from employing the monitoring step by following the path of the prior art of record which neither inherently provides, teaches, discloses, nor enables it (B). The elected claimed method with its step of monitoring vitamin C consumption is enabled by the labeling step and the functional relationship between labeling and vitamin C in a dose of ibuprofen. Therefore, the elected claimed method with its step of monitoring vitamin C consumption is nonobvious and supportive of patentability, since it is not disclosed by the prior art of record, which teaches away from monitoring vitamin C consumption and it i) satisfies a long felt need, and ii) solves the problem, which others have failed to solve of not being able to monitor and regulate vitamin C consumption from consuming ibuprofen pain reliever. Thus, a case of prima facie obviousness is not established by the prior art of record because it teaches away from the functional relationship that is required to carry out the elected claimed method, and the steps of the elected claimed method, Tec Air, In re Ngai, Goodyear Tire & Rubber, Pro-Mold & Tool Co and Transmatic, Inc. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause, since it does not establish a prima facie case of obviousness.

D) There is no teaching to establish a prima facie case of obviousness, if a reference suggests a line of development teaching away from (3) a result sought by the applicant, Tec Air. And, for printed matter and substrate the question is whether there exists any new and unobvious functional relationship between them, In re Miller 164 USPQ 46, 49 (CCPA 1969), In re Gulack 217 USPQ 401, 404 (CAFC 1983) and In re Ngai at 1864. The elected claimed method provides a

new and unobvious functional relationship between the labeling of vitamin C in a unit dose, and vitamin C in the dose. Yeh et al and the prior art of record do not disclose monitoring the amount of vitamin C consumed with a dose of ibuprofen, or labeling the amount of vitamin C in a dose of ibuprofen and providing a functional relationship between the labeling and the vitamin C in a dose of ibuprofen. And, a dose of ibuprofen provided without labeling indicating the amount and percent daily of vitamin C would be unable to produce the results sought by Applicant of enabling consumers to regulate their consumption of vitamin C. Since, regulating consumption of vitamin C requires monitoring it. And, monitoring it requires labeling it, and a functional relationship between the labeling indications and the vitamin C in a dose. So, it would not have been obvious to one of ordinary skill in the prior art of record to employ the monitoring step into a method to produce the result sought by Applicant of regulating vitamin C consumption, since the prior art of record (3) suggests development without monitoring the amount of vitamin C consumed with a dose of ibuprofen, or labeling the amount of vitamin C in a dose of ibuprofen and providing a functional relationship between the labeling and the vitamin C in a dose of ibuprofen, which are needed for monitoring vitamin C consumption. And, without monitoring vitamin C consumption it is unlikely to produce the results sought by Applicant of regulating vitamin C consumption, since monitoring vitamin C consumption is needed to regulate it. Thus, there is no teaching to establish a prima facie case of obviousness, since Yeh et al do not disclose the functional relationship needed for monitoring vitamin C consumption, and teach away by (3) suggesting development unlikely to produce the result sought by Applicant, Tec Air, In re Ngai, Gulack and In re Miller. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause, since it does not establish a prima facie case of obviousness.

Motivation To Administer The Composition Of Yeh et al Does Not Provide Monitoring Vitamin C

[X] [1] One of ordinary skill in the art having been motivated to administer the analgesic composition of Yeh et al for treating pain, would not have been

motivated to regulate vitamin C consumption, since it is not disclosed, or enabled. Yeh et al do not inherently provide, disclose or enable regulating vitamin C consumption, or monitoring vitamin C consumed in a dose of ibuprofen, or a) labeling the amount or percent daily value of vitamin C in a dose of ibuprofen, and b) a functional relationship between the labeling indicating the amount and percent daily value of vitamin C, and vitamin C in the unit dose of ibuprofen, which are needed to enable regulating vitamin C consumption. Consequently, one of ordinary skill in the art would not have been motivated to administer the analgesic composition of Yeh et al to produce the result of regulating vitamin C consumption sought by Applicant, since they do not disclose regulating vitamin C consumption, or enabling it. Rather, they teach away from regulating vitamin C consumption by (3) suggesting development unlikely to produce that result, by not disclosing it, or enabling it. Therefore, one of ordinary skill in the art would not have been motivated to regulate vitamin C consumption by administering the analgesic composition of Yeh et al for treating pain, since it is not inherently provided, disclosed or enabled. [2] Administering the analgesic composition of Yeh et al does not provide monitoring consumption of vitamin C, which is needed to regulate vitamin C consumption. And, it does not provide labeling the amount and percent daily value of vitamin C in a dose of ibuprofen, and a functional relationship between the labeling and vitamin C in the dose, which are needed to monitor vitamin C consumption. Therefore, administering the analgesic composition of Yeh et al does not provide motivation for regulating vitamin C consumption, since it does not enable monitoring vitamin C consumption or regulating vitamin C consumption. Consequently, one of ordinary skill in the art being motivated to administer the analgesic composition of Yeh et al for treating pain does not suggest motivation for monitoring vitamin C consumption or regulating vitamin C consumption, since they are neither inherently provided, disclosed nor enabled. [3] Administering the analgesic composition of Yeh et al does not enable monitoring vitamin C consumption, which teaches away by (2) leading in a direction divergent from of path taken by Applicant of monitoring vitamin C consumption by labeling the amount and

percent daily value of vitamin C in a dose of ibuprofen, to provide a functional relationship between labeling and vitamin C in the dose, which enables monitoring consumption of the vitamin C. Administering the analgesic composition of Yeh et al, does not provide or enable the elected claimed method, since they do not disclose monitoring vitamin C consumption, or enabling it by: a) labeling an amount and percent daily value of vitamin C in a dose of ibuprofen, and b) providing a functional relationship between labeling and vitamin C in a dose of ibuprofen. And, administering the analgesic composition of Yeh et al does not enable regulating consumption of vitamin C, while consuming the dose of ibuprofen, since it requires monitoring consumption of vitamin C to regulate it. Rather, Yeh et al teaches away by (3) suggesting a line of development of labeling ibuprofen, that is unlikely to produce the result sought by Applicant, of enabling regulation of vitamin C consumption, which requires a) monitoring consumption of vitamin C in a dose of ibuprofen, b) labeling an amount and percent daily value of vitamin C in the dose of ibuprofen, and c) providing a functional relationship between labeling and vitamin C in the dose. [4]The elected claimed method provides a new and unobvious functional relationship between labeling of vitamin C in a dose of ibuprofen, and the vitamin C in the dose, which is needed to monitor consumption of vitamin C. And, administering the analgesic composition of Yeh et al does not provide a functional relationship between labeling, and vitamin C in a dose of ibuprofen, which is needed to monitor vitamin C consumption, and is provided by the elected claimed method. [5] Administering the analgesic composition of Yeh et al does not inherently monitor or enable monitoring of vitamin C consumed with a dose of ibuprofen. It does not a) label an amount or percent daily value of vitamin C in a dose of ibuprofen, and b) provide a functional relationship between labeling and vitamin C in a dose of ibuprofen, which are needed to monitor vitamin C consumption. Consequently, a person of ordinary skill would be (1) discouraged from following the path of administering the analgesic composition of Yeh et al to monitor vitamin C consumption, (as provided by the elected claimed method), since the

consumption of the vitamin C, or monitoring consumption of the vitamin C, as required by the elected claimed method. Commercially available products based on the prior art of record do not include vitamin C, and their labeling does not indicate an amount of vitamin C (or any other nutritional supplement) in a dose of ibuprofen, or enable monitoring consumption of vitamin C (or any other nutritional supplement), as required by the elected claimed method.

The elected claimed method gives the previously unknown practical uses of monitoring vitamin C consumption while consuming ibuprofen. The elected claimed method has objective criteria for patentability in the failure of others to find a solution to the problem of not being able to monitor vitamin C consumption while consuming ibuprofen, or make the invention of the claimed method. The claimed method solves problems and satisfies needs felt for decades of consuming ibuprofen.

The claims are believed to be allowable. Such action is respectfully requested.

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steps and functional relationship needed are not provided or enabled by administering the analgesic composition of Yeh et al.

[1] There is no teaching to establish a prima facie case of obviousness, if a reference suggests a line of development teaching away from (3) a result sought by the applicant, Tec Air. And, for printed matter and substrate the question is whether there exists any new and unobvious functional relationship between them, In re Miller 164 USPQ 46, 49 (CCPA 1969), In re Gulack 217 USPQ 401, 404 (CAFC 1983) and In re Ngai at 1864. Yeh et al, and the prior art of record do not inherently provide, disclose or enable monitoring or regulating vitamin C consumption. They do not disclose labeling the amount or percent daily value of vitamin C in a dose of ibuprofen, or a functional relationship between the labeling indicating the amount and percent daily value of vitamin C, and vitamin C in the unit dose of ibuprofen. And, a dose of ibuprofen and vitamin C provided without labeling the amount of vitamin C would be unable to produce the results sought by Applicant of enabling consumers to regulate their consumption of vitamin C. Therefore, the elected claimed method provides a new and unobvious functional relationship between the labeling indicating the amount and percent daily value of vitamin C, and vitamin C in the unit dose. So, [1] one of ordinary skill in the art having been motivated to administer the analgesic composition of Yeh et al for treating pain, would not have been motivated to regulate vitamin C consumption, since it is not disclosed, or enabled. Yeh et al do not inherently provide, disclose or enable regulating vitamin C consumption, or monitoring vitamin C consumed in a dose of ibuprofen, or a) labeling the amount and percent daily value of vitamin C in a dose of ibuprofen, and b) a functional relationship between the labeling indicating the amount and percent daily value of vitamin C, and vitamin C in the unit dose of ibuprofen, which are needed to enable regulating vitamin C consumption. And, one of ordinary skill in the art would not have been motivated to administer the analgesic composition of Yeh et al to produce the result of regulating vitamin C consumption sought by Applicant, since they do not disclose regulating vitamin C consumption, or enabling it. Rather, they teach away from regulating vitamin C consumption by

(3) suggesting development unlikely to produce that result, by not disclosing it, or enabling it. Therefore, one of ordinary skill in the art would not have been motivated to regulate vitamin C consumption by administering the analgesic composition of Yeh et al for treating pain, since it is not inherently provided, disclosed or enabled. Thus, there is no teaching to establish a prima facie case of obviousness, since Yeh et al teach away by (3) suggesting development unlikely to produce the result sought by Applicant, Tec Air, In re Ngai, Gulack and In re Miller. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause, since they do not establish a prima facie case of obviousness.

[2] To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art, In re Royka, 490 F2d 981, 180 USPQ 580 (CCPA 1974), MPEP 2143.3. Neither Yeh et al, nor the prior art of record discloses a functional relationship between any vitamin C in a dose and labeling, or labeling an amount or percent daily value of vitamin C. Administering the analgesic composition of Yeh et al for treating pain does not inherently provide, disclose or enable monitoring consumption of vitamin C, regulation of vitamin C consumption, labeling of the amount and percent daily value of vitamin C in a dose of ibuprofen, or a functional relationship between the labeling and vitamin C in a dose. So, [2] Administering the analgesic composition of Yeh et al does not provide monitoring consumption of vitamin C, which is needed to regulate vitamin C consumption. And, it does not provide labeling the amount and percent daily value of vitamin C in a dose of ibuprofen, and a functional relationship between the labeling and vitamin C in the dose, which are needed to monitor vitamin C consumption. Therefore, administering the analgesic composition of Yeh et al does not provide motivation for regulating vitamin C consumption, since it does not enable monitoring vitamin C consumption or regulating vitamin C consumption. Consequently, one of ordinary skill in the art being motivated to administer the analgesic composition of Yeh et al for treating pain does not suggest motivation for monitoring vitamin C consumption or regulating vitamin C consumption, since they are neither

inherently provided, disclosed nor enabled. Thus, *prima facie* obviousness of the claimed invention is not established, since all of the claim limitations are not taught or suggested by the prior art, *In re Royka*, MPEP 2143.3. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause, since they do not establish *prima facie* obviousness of the elected claimed invention.

[3] There is no teaching to establish a *prima facie* case of obviousness, if a reference teaches away from (2) a path taken or (3) a result sought by the applicant, Tec Air. Yeh et al disclose compositions including ibuprofen. Neither Yeh et al nor the prior art of record disclose a functional relationship between any vitamin C in a dose and labeling, or labeling an amount or percent daily value of vitamin C, or a method for monitoring vitamin C consumed with ibuprofen, or regulating vitamin C consumption. So, [3] administering the analgesic composition of Yeh et al does not enable monitoring vitamin C consumption, which teaches away by (2) leading in a direction divergent from of path taken by Applicant of monitoring vitamin C consumption by labeling the amount and percent daily value of vitamin C in a dose of ibuprofen, to provide a functional relationship between labeling and vitamin C in the dose, which enables monitoring consumption of the vitamin C. Administering the analgesic composition of Yeh et al, does not provide or enable the claimed method, since they do not disclose monitoring vitamin C consumption, or enabling it by: a) labeling an amount and percent daily value of vitamin C in a dose of ibuprofen, and b) providing a functional relationship between labeling and vitamin C in a dose of ibuprofen. And, administering the analgesic composition of Yeh et al does not enable regulating consumption of vitamin C, while consuming the dose of ibuprofen, since it requires monitoring consumption of vitamin C to regulate it. Rather, Yeh et al teaches away by (3) suggesting a line of development of labeling ibuprofen, that is unlikely to produce the result sought by Applicant, of enabling regulation of vitamin C consumption, which requires a) monitoring consumption of vitamin C in a dose of ibuprofen, b) labeling an amount and percent daily value of vitamin C in the dose of ibuprofen, and c) providing a

functional relationship between labeling and vitamin C in the dose. Thus, administering an ibuprofen of Yeh et al leads in a direction divergent from of path taken by Applicant in the steps of the claimed method, and is unlikely to produce the result sought by Applicant, and Tec Air. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause, since they do not establish a prima facie case of obviousness.

[4] For printed matter and substrate the question is whether there exists any new and unobvious functional relationship between them, In re Miller 164 USPQ 46, 49 (CCPA 1969), In re Gulack 217 USPQ 401, 404 (CAFC 1983) and In re Ngai at 1864. Differences between the invention and the prior art cited against it cannot be ignored merely because they reside in printed matter, In re Gulack at 403. Neither Yeh et al, SS Pharmaceutical nor Tsunoda discloses or suggests labeling an amount or percent daily value of the vitamin C. And, they do not disclose or suggest a functional relationship between vitamin C in a dose and labeling indications. In the elected claimed method labeling the amount and percent daily value of vitamin C in the labeling indications would not achieve its monitoring, and regulating purposes without the corresponding vitamin C in the dose of ibuprofen provided in the enclosure having the labeling indications. And, the vitamin C in the dose of ibuprofen provided without the labeling would similarly be unable to produce the desired result of enabling consumers to monitor and regulate their consumption of vitamin C. So, [4] the elected claimed method provides a new and unobvious functional relationship between labeling the amount and percent daily value of vitamin C in a dose of ibuprofen, and the vitamin C in the dose, which is needed to monitor consumption of vitamin C. And, administering the analgesic composition of Yeh et al does not provide a functional relationship between labeling, and vitamin C in a dose of ibuprofen, which is needed to monitor vitamin C consumption, and is provided by the elected claimed method. Thus, the elected claimed method provides a new and unobvious functional relationship, which is supportive of patentability, In re Ngai, Gulack and In re Miller. Accordingly, the Claims are not obvious under 35 USC

103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause, since there is a new and unobvious functional relationship, which is supportive of patentability.

[5] A case of prima facie obviousness is not established, if a reference teaches away from the combination when a person of ordinary skill, upon reading the reference, would be (1) discouraged from following the path set out in the reference, Tec Air. Yeh et al disclose a composition including ibuprofen. Neither Yeh et al, SS Pharmaceutical nor Tsunoda inherently provides, discloses or enables the claimed method of monitoring consumption of vitamin C with ibuprofen, or a functional relationship between labeling and vitamin C in a dose of ibuprofen needed for monitoring vitamin C consumption, or the steps of the claimed method of labeling an amount of vitamin C in a dose of ibuprofen, and consuming the dose of ibuprofen from the labeled enclosure and monitoring the vitamin C consumed. So, [5] administering the analgesic composition of Yeh et al does not inherently monitor or enable monitoring of vitamin C consumed with a dose of ibuprofen. It does not a) label an amount or percent daily value of vitamin C in a dose of ibuprofen, and b) provide a functional relationship between labeling and vitamin C in a dose of ibuprofen, which are needed to monitor vitamin C consumption. Consequently, a person of ordinary skill would be (1) discouraged from following the path of administering the analgesic composition of Yeh et al to monitor vitamin C consumption, (as provided by the elected claimed method), since the steps and functional relationship needed are not provided or enabled by administering the analgesic composition of Yeh et al. Thus, a case of prima facie obviousness is not established by administering a composition of Yeh et al, since they teach away from the elected claimed method, by not enabling it, Tec Air. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause, since they do not establish a prima facie case of obviousness.

Administering Composition Of Yeh et al Does Not Inherently Monitor Vitamin C

[XI] Administering a composition of Yeh et al does not inherently provide or enable a method of monitoring vitamin C consumption, or any of the steps of the claimed method of a) labeling the amount and percent daily value of the vitamin

C in a dose of ibuprofen, b) consuming the dose from the labeled enclosure and c) monitoring the vitamin C consumed. Administering a composition of Yeh et al (2) leads in a direction divergent from the path that was taken by Applicant, of monitoring of vitamin C consumption, since administering a composition of Yeh et al does not inherently provide or enable monitoring of vitamin C consumption, or the step of labeling amount of vitamin C in a dose of ibuprofen, and the functional relationship between labeling and vitamin C in a dose of ibuprofen, which are needed to carry out monitoring of vitamin C consumption. And, administering a composition of Yeh et al (3) suggests development unlikely to inherently produce the results sought by Applicant of enabling regulation of vitamin C consumption and regulating vitamin C consumption, since it does not inherently monitor and regulate vitamin C consumption, or inherently enable monitoring and regulating vitamin C consumption, or inherently provide a functional relationship between labeling and vitamin C in a dose of ibuprofen pain reliever, which is needed to monitor and regulate vitamin C consumption. Administering the composition of Yeh et al does not inherently imbue one of ordinary skill in the art with knowledge of the elected claimed method of monitoring vitamin C nutritional supplement consumed in a dose of ibuprofen pain reliever, or a functional relationship between labeling and vitamin C in a dose of ibuprofen pain reliever, which is needed to monitor the vitamin C consumed, when no prior art reference of record conveys or suggests that knowledge.

All of the features of the claimed invention must be shown to establish prima facie obviousness of the invention, In re Royka, 490 F2d 981, 180 USPQ 580 (CCPA 1974), MPEP 2143.3. All of the claims require labeling a unit dose of ibuprofen and vitamin C, consuming it and monitoring vitamin C consumption. Yeh et al discloses compositions including ibuprofen, and do not disclose indicating an amount or percent daily value of the vitamin C, monitoring consumption of vitamin C (or any other nutritional supplement), or regulating consumption of vitamin C. Neither Yeh et al, SS Pharmaceutical nor Tsunoda discloses the elected claimed method of monitoring consumption of vitamin C with ibuprofen, or a functional relationship used by the claimed method between

vitamin C in a dose of ibuprofen and its labeling, or the steps of the claimed method of labeling an amount and percent daily value of vitamin C in a dose of ibuprofen, consuming the dose of ibuprofen from the labeled enclosure and monitoring the vitamin C consumed. Administration of an ibuprofen composition of Yeh et al to patients does not inherently provide or enable a method of monitoring vitamin C consumption, or any of the steps of the elected claimed method of labeling the amount and percent daily value of the vitamin C in a dose of ibuprofen, consuming the dose from the labeled enclosure and monitoring the vitamin C consumed. So, administering a composition of Yeh et al does not inherently provide or enable a method of monitoring vitamin C consumption, or any of the steps of the claimed method of a) labeling the amount and percent daily value of the vitamin C in a dose of ibuprofen, b) consuming the dose from the labeled enclosure and c) monitoring the vitamin C consumed. Thus, *prima facie* obviousness of the claimed invention is not established, since all of the claim limitations are not taught or suggested by the prior art of record, In re Royka, MPEP 2143.3. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause, since they do not establish *prima facie* obviousness of the elected claimed invention.

There is no teaching to establish *prima facie* obviousness, if a reference teaches away by (2) leading in a direction divergent from the path that was taken by Applicant, or (3) suggesting a line of development flowing from its disclosure unlikely to be productive of the result sought by the applicant, Tec Air. Neither Yeh et al, SS Pharmaceutical nor Tsunoda discloses the elected claimed method of monitoring consumption of vitamin C with ibuprofen, or a functional relationship used by the claimed method between labeling and vitamin C in a dose of ibuprofen, or the steps of the claimed method of labeling an amount and percent daily value of vitamin C in a dose of ibuprofen, consuming the dose of ibuprofen from the labeled enclosure and monitoring the vitamin C consumed. Administering a composition of Yeh et al (or SS Pharmaceutical or Tsunoda) does not inherently enable monitoring or regulating vitamin C consumption. Yeh et al do not disclose regulating vitamin C consumption, or a method for

monitoring vitamin C consumed with ibuprofen from an enclosure having labeling enabling monitoring of vitamin C consumption, or a functional relationship between any vitamin C in a dose and labeling, or labeling an amount and percent daily value of vitamin C (or any other nutritional supplement). Administering a composition of Yeh et al (or SS Pharmaceutical or Tsunoda) does not inherently monitor of vitamin C consumption, as required by the elected claimed method, since it does not inherently enable monitoring of vitamin C consumption, or inherently provide the step of labeling amount and percent daily value of vitamin C in a dose of ibuprofen, and the functional relationship between labeling and vitamin C in a dose of ibuprofen, which are needed to carry out monitoring of vitamin C consumption. And, administering a composition of Yeh et al (or SS Pharmaceutical or Tsunoda) does not inherently produce the results sought by Applicant of regulating consumption of vitamin C, since it does not inherently provide or enable regulating vitamin C consumption, or inherently provide the steps and functional relationship needed to regulate vitamin C consumption. So, administering a composition of Yeh et al (or SS Pharmaceutical or Tsunoda) (2) leads in a direction divergent from the path that was taken by Applicant, of monitoring of vitamin C consumption, since administering a composition of Yeh et al does not inherently provide or enable monitoring of vitamin C consumption, or the step of labeling amount and percent daily value of vitamin C in a dose of ibuprofen, and the functional relationship between labeling and vitamin C in a dose of ibuprofen, which are needed to carry out monitoring of vitamin C consumption. And, administering a composition of Yeh et al (3) (or SS Pharmaceutical or Tsunoda) suggests development unlikely to inherently produce the results sought by Applicant of enabling regulation of vitamin C consumption and regulating vitamin C consumption, since it does not inherently monitor and regulate vitamin C consumption, or inherently enable monitoring and regulating vitamin C consumption, or inherently provide a functional relationship between labeling and vitamin C in a dose of ibuprofen pain reliever, which is needed to monitor and regulate vitamin C consumption. Thus, there is no teaching to establish prima facie obviousness in administration of the

composition of Yeh et al (or SS Pharmaceutical or Tsunoda) since it (2) leads in a direction divergent from the path that was taken by Applicant, and (3) suggests development unlikely to produce the result sought by Applicant, Tec Air.

Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause, since they do not establish a prima facie case of obviousness.

It is legal error to use the inventor's patent specification teaching of both a novel and unobvious invention as though it were prior art in order to make claims appear to be obvious In re Pleuddemann, 901 F2d 823, 828, 15 USPQ 2d 1738, 1742 (Fed. Cir 1990). To imbue one of ordinary skill in the art with knowledge of the invention when no prior art reference of record conveys or suggests that knowledge is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against the teacher, In re Fine, 837 F2d 1071, 1075, 5 USPQ 2d 1598, 1600 (Fed. Cir. 1988). One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention, In re Fine at 1600. Neither Yeh et al, SS Pharmaceutical nor Tsunoda discloses or inherently provides the elected claimed method of monitoring consumption of vitamin C nutritional supplement consumed in a dose of ibuprofen pain reliever, or a functional relationship used by the claimed method between labeling and vitamin C in the dose, or the steps of the claimed method of labeling an amount and percent daily value of vitamin C in the dose, consuming the dose from the labeled enclosure and monitoring the vitamin C consumed. So, administering the composition of Yeh et al, SS Pharmaceutical or Tsunoda does not inherently imbue one of ordinary skill in the art with knowledge of the elected claimed method of monitoring vitamin C nutritional supplement consumed in a dose of ibuprofen pain reliever, or a functional relationship between labeling and vitamin C in a dose of ibuprofen pain reliever, which is needed to monitor the vitamin C consumed, when no prior art reference of record conveys or suggests that knowledge. Thus, the rejection is legal error falling victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against the teacher, and prohibitively selects by using

hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the elected claimed invention, In re Pleuddemann and In re Fine. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause, since they are without any teaching leading thereto other than the inventor's patent specification.

There Is An Unobvious Functional Relationship Between The Labeling And Vitamin C

[XII] Applicant is entitled to patent the elected claimed method for monitoring consumption of vitamin C with ibuprofen by labeling a known composition, consuming a dose from the labeled product, and monitoring the vitamin C consumed, since i) the elected claimed method, its steps and the functional relationship needed to carry it out are not disclosed by the prior art of record, ii) the prior art of record teaches away from the elected claimed method, iii) the elected claimed method satisfies a long felt need, iv) the elected claimed method solves the problem, which others have failed to solve of not being able to monitor or regulate vitamin C consumption from consuming ibuprofen pain reliever, or make the invention of the elected claimed method. And, the labeling and its functional relationship to the vitamin C in the dose of ibuprofen are new and unobvious making the elected claimed method of monitoring consumption of vitamin C in a dose of ibuprofen patentable. Consequently, it follows that the elected claimed method of monitoring consumption of vitamin C by labeling a product enclosing a known ibuprofen composition is not obvious, especially in view of Krause, which discloses food labeling, but does not disclose labeling the amount of vitamin C in a dose of ibuprofen, a functional relationship between labeling and vitamin C in a dose of ibuprofen, or monitoring vitamin C consumed with the dose of ibuprofen. And, the elected claimed method is patentable, since it cures defects of a product in use for decades. The step of the elected claimed method of labeling indicating the amount and percent daily value of vitamin C in a dose of ibuprofen provides a nonobvious functional relationship between labeling and vitamin C in the dose, which enables monitoring vitamin C consumption, and cures defects of a product in use for decades. And, monitoring vitamin C

consumption produces the desired result of enabling consumers to regulate their consumption of vitamin C with ibuprofen. Applicant is entitled to a patent on the elected claimed method of monitoring vitamin C consumed from the novel and nonobvious product enclosing a dose of ibuprofen and vitamin C, and labeled with the amount and percent daily value of vitamin C in the dose, since both the labeled product used and the elected claimed method of monitoring vitamin C consumed are not known or obvious in view of the prior art of record.

i) The claimed method, its steps and the functional relationship needed to carry it out are not disclosed by the prior art of record. For printed matter and substrate the question is whether there exists any new and unobvious functional relationship between them, In re Miller 164 USPQ 46, 49 (CCPA 1969), In re Gulack 217 USPQ 401, 404 (CAFC 1983) and In re Ngai at 1864. In the elected claimed method labeling the amount and percent daily value of vitamin C would not achieve its monitoring, and regulating purposes without the corresponding amount of vitamin C in the dose of ibuprofen provided in the enclosure having the labeling. And, the dose of vitamin C with ibuprofen provided without labeling the amount and percent daily value of vitamin C in the dose would similarly be unable to produce the desired result of enabling consumers to monitor and regulate their consumption of vitamin C with ibuprofen. All of the features of the elected claimed invention must be shown to establish *prima facie* obviousness of the invention, In re Royka, 490 F2d 981, 180 USPQ 580 (CCPA 1974), MPEP 2143.3. All of the claims require labeling a unit dose of ibuprofen and vitamin C, consuming it and monitoring vitamin C consumption. Neither Yeh et al, SS Pharmaceutical nor Tsunoda discloses the elected claimed method of monitoring consumption of vitamin C with ibuprofen, or the functional relationship, used by the elected claimed method, between labeling and vitamin C in a dose of ibuprofen, or the steps of the elected claimed method of labeling an amount and percent value of vitamin C in a dose of ibuprofen, consuming the dose of ibuprofen from the labeled enclosure and monitoring the vitamin C consumed. Krause teaches well known information about labeling food. However, Krause does not disclose the functional relationship or steps required by the elected

claimed method of: the step of labeling the amount and percent daily value of vitamin C in a dose of ibuprofen, the functional relationship between labeling and vitamin C in the dose of ibuprofen, or the step of monitoring consumption of vitamin C in the dose of ibuprofen. Therefore, the elected claimed method, and its steps and the functional relationship needed to carry it out are not disclosed by the prior art of record.

ii) The prior art of record teaches away from the claimed method. There is no teaching to establish a prima facie case of obviousness, if a reference teaches away from (2) a path taken or (3) a result sought by the applicant, Tec Air. Yeh et al, SS Pharmaceutical and Tsunoda do not disclose labeling an amount or percent daily value of vitamin C in a dose of ibuprofen, or a functional relationship between labeling and vitamin C in a dose of ibuprofen needed to monitor vitamin C consumption, or consuming the dose of ibuprofen from the labeled product and monitoring vitamin C consumed, as required by the elected claimed method. Yeh et al, SS Pharmaceutical and Tsunoda teach away (2) leading in a direction divergent from of path taken by Applicant, by disclosing a dose of ibuprofen, but without either inherently providing, teaching, or disclosing a) monitoring vitamin C consumed with ibuprofen, as provided by the elected claimed method or b) labeling an amount and percent daily value of vitamin C in a dose of ibuprofen, and c) a functional relationship between labeling and vitamin C in the dose of ibuprofen, which are needed for monitoring consumption of vitamin C in a dose of ibuprofen. Also, the prior art of record, by not disclosing, inherently providing or enabling monitoring or regulating vitamin C consumption, teach away suggesting a line of development that is unlikely to produce the (3) results sought by Applicant, of enabling the consumer to regulate consumption of vitamin C, by a method for monitoring consumption of vitamin C with ibuprofen from an enclosure having labeling, which is functionally related to the amount of vitamin C in the dose of ibuprofen. Therefore, the prior art of record teaches away from the elected claimed method, by not disclosing, inherently providing or enabling monitoring or regulating vitamin C consumption.

iii) The elected claimed method satisfies a long felt need. In holding an

invention to be patentable the Court stated that during a period of half a century of use of a product no one devised a method of curing its defects, Goodyear Tire & Rubber Co. v Ray-O-Vac Co. 321 US 275 (1944). Similarly, during decades of use of ibuprofen products no one devised a method of curing the defects. These defects result in its consumers' inability to monitor or regulate consumption of the vitamin C. Consequently, the consumers cannot monitor or regulate their consumption of vitamin C, since the amount of vitamin C, if any, is not indicated, Attachments B and C, and Yeh et al. Ibuprofen has been used since 1969, see Attachment E. Ibuprofen with antioxidant was disclosed in 1993 by Motola US patent 5185373 (Attachment A). So, after decades of inability to monitor or regulate consumption of the vitamin C, the elected claimed method monitors vitamin C consumption and enables consumers to regulate it by consuming a unit dose of ibuprofen pain reliever and vitamin C nutritional supplement from an enclosure having labeling indicating the amount and percent daily value of vitamin C, and monitoring the vitamin C consumed. Therefore, the claimed method satisfies a long felt need.

iv) The elected claimed method solves the problem, which others have failed to solve of not being able to monitor or regulate vitamin C consumption from consuming ibuprofen pain reliever, or make the invention of the elected claimed method. The objective criteria for patentability include failure of others to find a solution to the problem, Pro-Mold & Tool Co v Great Lakes Plastics, Inc. 75 F3d 1568, 1572 (Fed Cir 1996). And, they include failure of others to make the invention, Transmatic, Inc v Gulton Indus., Inc. 53 F3d 1270, 1275 (Fed Cir 1995). The elected claimed method has objective criteria for patentability in the failure of others to find a solution to the problem of not being able to monitor or regulate vitamin C consumption from consuming ibuprofen pain reliever, which may contain vitamin C, or make the invention of the elected claimed method. Therefore, the elected claimed method solves the problem, which others have failed to solve of not being able to monitor or regulate vitamin C consumption from consuming ibuprofen pain reliever, or make the invention of the claimed method.

So, Applicant is entitled to patent the elected claimed method for monitoring consumption of vitamin C with ibuprofen by labeling a known composition, consuming a dose from the labeled product, and monitoring the vitamin C consumed, since i) the elected claimed method, its steps and the functional relationship needed to carry it out are not disclosed by the prior art of record, ii) the prior art of record teaches away from the elected claimed method, iii) the elected claimed method satisfies a long felt need, iv) the elected claimed method solves the problem, which others have failed to solve of not being able to monitor or regulate vitamin C consumption from consuming ibuprofen pain reliever, or make the invention of the elected claimed method. And, the labeling and its functional relationship to the vitamin C in the dose of ibuprofen are new and unobvious making the elected claimed method of monitoring consumption of vitamin C in a dose of ibuprofen patentable. Consequently, it follows that the elected claimed method of monitoring consumption of vitamin C by labeling a product enclosing a known ibuprofen composition is not obvious, especially in view of Krause, which discloses food labeling, but does not disclose labeling the amount of vitamin C in a dose of ibuprofen, a functional relationship between labeling and vitamin C in a dose of ibuprofen, or monitoring vitamin C consumed with the dose of ibuprofen. And, the elected claimed method is patentable, since it cures defects of a product in use for decades. The step of the claimed method of labeling indicating the amount and percent daily value of vitamin C in a dose of ibuprofen provides a nonobvious functional relationship between labeling and vitamin C in the dose, which enables monitoring vitamin C consumption, and cures defects of a product in use for decades. And, monitoring vitamin C consumption produces the desired result of enabling consumers to regulate their consumption of vitamin C. Thus, the elected claimed method provides a new and unobvious labeling and functional relationship, and cures defects of a product in use for decades, which are supportive of patentability, In re Ngai, Gulack, In re Miller, In re Royka, Tec Air, Pro-Mold & Tool Co, Transmatic, Inc, and Goodyear Tire & Rubber Co. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause, since they do not

disclose the new and unobvious functional relationship, which is supportive of patentability, and cure defects in a product in use for decades cured by the elected claimed method.

No Motivation To Monitor, Since No Vitamin C Regimen Is Intended In The Art

[XIII] One of ordinary skill in the art would not have been motivated to employ the step of monitoring of vitamin C, since the labeling system of the ibuprofen pain reliever prior art is not intended for patients to grasp and understand the daily regimen of regulating consumption of vitamin C nutritional supplement and thereby improve the adherence to the daily regimen. And, in order to be adherent to the daily regimen, the patients have to consciously “watch and check on” or monitor what he or she is taking (consumption): no more or no less than what labeling the amount of vitamin C describes in functional relation to the vitamin C in the dose of ibuprofen to enable monitoring the vitamin C consumed. Therefore, the monitoring step of the elected claimed method is not met by the disclosure of the Yeh et al, SS Pharmaceutical, Tsunoda or Krause, since the labeling system of the ibuprofen pain reliever prior art does not indicate the amount of vitamin C in a dose of ibuprofen, or provide a functional relationship between the labeling and vitamin C in the dose, and is not intended for patients to grasp and understand the daily regimen of regulating consumption of vitamin C and thereby improve the adherence to the daily regimen. And, the prior art (3) suggests development unlikely to produce the result sought by Applicant of regulating vitamin C consumption, since it does not disclose regulating vitamin C consumption, or the functional relationship and steps needed for regulation of vitamin C consumption of: a) labeling the amount of vitamin C in a dose of ibuprofen, b) a functional relationship between labeling and the vitamin C in the dose of ibuprofen, and c) monitoring the vitamin C consumed. Neither labeling an amount of vitamin C (or any other nutritional supplement) in a dose of ibuprofen, nor monitoring (“watching and checking on”) its consumption, are shown in the prior art or labeling of commercial products based thereon (Attachments B and C), as required by the elected claimed method.

There is no teaching to establish a prima facie case of obviousness, if a

reference suggests a line of development teaching away from (3) a result sought by the applicant, Tec Air. And, for printed matter and substrate the question is whether there exists any new and unobvious functional relationship between them, In re Miller 164 USPQ 46, 49 (CCPA 1969), In re Gulack 217 USPQ 401, 404 (CAFC 1983) and In re Ngai at 1864. Neither Yeh et al, SS Pharmaceutical, Tsunoda, Krause nor commercial ibuprofen pain reliever (Attachments B and C) disclose monitoring vitamin C consumption, or labeling the amount or percent daily value of vitamin C in a dose of ibuprofen, or functional relationship between labeling and vitamin C in a dose of ibuprofen, a regimen of regulating consumption of vitamin C, or a vitamin C therapy. And, a dose of ibuprofen provided without labeling the amount and percent daily value of vitamin C would be unable to produce the results sought by Applicant of enabling consumers to monitor and regulate their consumption of vitamin C. Therefore, the elected claimed method provides a new and unobvious functional relationship between the labeling, and vitamin C in the dose. And, the prior art by not disclosing monitoring vitamin C consumed or enabling it by labeling the amount and percent daily value of vitamin C and providing a functional relationship between the labeling, and vitamin C in the dose, suggests a line of development teaching away from (3) results sought by Applicant of monitoring and regulating vitamin C consumed. So, one of ordinary skill in the art would not have been motivated to employ the step of monitoring of vitamin C, since the labeling system of the ibuprofen pain reliever prior art is not intended for patients to grasp and understand the daily regimen of regulating consumption of vitamin C nutritional supplement and thereby improve the adherence to the daily regimen. And, in order to be adherent to the daily regimen, the patients have to consciously "watch and check on" or monitor what he or she is taking (consumption): no more or no less than what labeling the amount and percent daily value of vitamin C describes in functional relation to the vitamin C in the dose of ibuprofen to enable monitoring the vitamin C consumed. Therefore, the monitoring step of the elected claimed method is not met by the disclosure of Yeh et al, SS Pharmaceutical, Tsunoda, or Krause, since the labeling system of the ibuprofen

pain reliever prior art does not indicate the amount or percent daily value of vitamin C (or any nutritional supplement) in a dose of ibuprofen, or provide a functional relationship between the labeling and vitamin C in the dose, and is not intended for patients to grasp and understand the daily regimen of regulating consumption of vitamin C and thereby improve the adherence to the daily regimen. And, the prior art (3) suggests development unlikely to produce the result sought by Applicant of regulating vitamin C consumption, since it does not disclose regulating vitamin C consumption, or the functional relationship and steps needed for regulation of vitamin C consumption of: a) labeling the amount and percent daily value of vitamin C in a dose of ibuprofen, b) a functional relationship between labeling and the vitamin C in the dose of ibuprofen, and c) monitoring the vitamin C consumed. Thus, there is no teaching to establish a prima facie case of obviousness, since Yeh et al teach away by (3) suggesting development unlikely to produce the result sought by Applicant, Tec Air, In re Ngai, Gulack and In re Miller. Accordingly, the Claims are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause, since they do not establish a prima facie case of obviousness.

All of the features of the claimed invention must be shown to establish prima facie obviousness of the invention, In re Royka, 490 F2d 981, 180 USPQ 580 (CCPA 1974), MPEP 2143.3. Neither a therapy of vitamin C, a regimen of regulating consumption of vitamin C, labeling an amount of vitamin C (or any other nutritional supplement), nor “watching and checking on” it or monitoring its consumption is disclosed, enabled or referred to by Yeh et al, SS Pharmaceutical, Tsunoda, Krause, or labeling of commercial products therefore (Attachments B and C). So, neither labeling an amount and percent daily value of vitamin C (or any other nutritional supplement) in a dose of ibuprofen, nor monitoring (“watching and checking on”) its consumption, are shown in the prior art or labeling of commercial products based thereon (Attachments B and C), as required by the elected claimed method. Thus, prima facie obviousness of the invention is not established since all of the features of the elected claimed invention are not shown by the prior art, In re Royka. Accordingly, the Claims

are not obvious under 35 USC 103 over Yeh et al, SS Pharmaceutical, Tsunoda and Krause.

SUMMARY

[I] The combination of SS Pharmaceutical, Tsunoda, and Yeh et al and Krause is improper, because nothing is disclosed or taught in them to suggest their combination. The combination of SS Pharmaceutical, Tsunoda, Yeh et al, and Krause does not have a reasonable expectation of success in arriving at the elected claimed method, since they do not disclose monitoring vitamin C consumed with ibuprofen or any of the steps of the elected claimed method. It would not have been obvious to use an antioxidant in a dose of ibuprofen as a nutritional supplement in a dose of ibuprofen, since it changes its operation from an antioxidant to prevent oxidation of ibuprofen in a dose of ibuprofen, to supplementing nutrition of the consumer of the dose of ibuprofen. No amount or percent daily value of antioxidant is indicated in labeling of commercially available ibuprofen, and the prior art of record does not disclose labeling indicating an amount or percent daily value of antioxidant.

[II] Yeh et al, SS Pharmaceutical, Tsunoda and Krause do not disclose, inherently provide, or enable the claimed method, its steps, or its desired results. And, they teach away by not enabling the claimed method, its steps, or its desired results. The elected claimed method solves problems, and it satisfies needs felt for decades of use of ibuprofen.

[III] The elected claimed method of monitoring the consumption of vitamin C with ibuprofen, is not obvious, since neither the method nor its steps of a) labeling an amount and percent daily value of vitamin C in a dose of ibuprofen, b) consuming the dose from the labeled product, and c) monitoring the amount of the vitamin C consumed with ibuprofen, are disclosed, inherently provided, or enabled by Yeh et al, SS Pharmaceutical, Tsunoda and Krause. The elected claimed method requires a product having labeling indicating the amount and percent daily value of vitamin C in a dose of ibuprofen, and the steps of labeling an enclosure with labeling indications indicating the amount and percent daily value of the vitamin C in a dose of ibuprofen, consuming the dose, and

monitoring the vitamin C consumed, and it produces the useful result of enabling the consumer to regulate consumption of the vitamin C, which are not disclosed by Yeh et al, SS Pharmaceutical, Tsunoda and Krause.

[IV] Yeh et al do not disclose a product having labeling indicating the amount of vitamin C in a dose of ibuprofen, as required by the claimed method. And, Yeh et al do not disclose steps of the claimed method of labeling the amount of vitamin C in a dose of ibuprofen, consuming the dose from the labeled product, or monitoring the amount of vitamin C consumed. Yeh et al disclose a dose having an amount of ibuprofen, and Krause disclose food labeling, but the prior art of record neither inherently provides, teaches, nor discloses labeling an amount of vitamin C in a dose of ibuprofen, a functional relationship between labeling and vitamin C in the dose of ibuprofen, consuming the dose from the product labeled, enabling monitoring vitamin C consumed or monitoring vitamin C consumed, as provided by the claimed method. Therefore, Yeh et al and Krause teach away by neither monitoring vitamin C consumed in a dose of ibuprofen, nor enabling it (2) leading in a direction divergent from of path taken by Applicant in the claimed method by labeling the amount of vitamin C in a dose of ibuprofen, which provides a functional relationship between labeling and vitamin C in the dose, that enables monitoring the amount of vitamin C consumed. And, by not enabling monitoring consumption of vitamin C, Yeh et al suggest a line of development that is unlikely to produce the (3) results sought by Applicant, of enabling the consumer to regulate consumption of vitamin C, since the consumer cannot regulate consumption of vitamin C without monitoring it, and Yeh et al do not enable monitoring it.

[V] While Krause teaches food labeling, Krause does not teach a method of monitoring vitamin C consumed with ibuprofen, or any of the steps of the claimed method of a) labeling the amount of vitamin C in a dose of ibuprofen, which provides a functional relationship with vitamin C in the dose, that enables monitoring vitamin C consumption, b) consuming the dose from the product labeled, and c) monitoring the amount of vitamin C consumed. And, the rejection in view of Krause imbues one of ordinary skill in the art with knowledge of a product

having labeling, which is functionally related to an amount of vitamin C in a dose of ibuprofen pain reliever, and used in a method for monitoring consumption of vitamin C in the dose. Yet, neither Krause nor any other prior art reference of record conveys or suggests that knowledge. And, the rejection has fallen victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against the teacher. Also, the rejection prohibitively selects by using hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention. In constructing the rejection the Examiner uses the inventor's patent specification teaching of both a novel and unobvious invention as though it were prior art in order to make claims appear to be obvious by combining Yeh et al, and Krause without any teaching in the references to combine them. They do not disclose a method of monitoring vitamin C consumed with ibuprofen, or a product having labeling, which is functionally related to the amount of vitamin C in a dose of ibuprofen, as provided by the claimed method.

[VI] [1] While Krause teaches food labeling, Krause does not disclose a dosage form for ibuprofen pain reliever and vitamin C nutritional supplement, or labeling a product for a dose of ibuprofen pain reliever and vitamin C nutritional supplement, or labeling which is functionally related to the amount of vitamin C in a dose of ibuprofen, or a method for monitoring vitamin C consumed in a dose of ibuprofen, or monitoring vitamin C consumption with ibuprofen, as provided by the claimed method. And, while Krause discloses food labeling, Krause (and Yeh et al) does not provide consumers and their administrators with a teaching which enables them to monitor or regulate consumption of vitamin C, or a container with labeling indicating the amount of vitamin C in a unit dose of ibuprofen, which enables monitoring consumption of vitamin C, as provided by the claimed method. Also, while Krause teaches food labeling, Krause does not provide consumers and their administrators with a teaching of a multiple use dosage form of ibuprofen pain reliever and vitamin C nutritional supplement, or a multiple use dosage form product of ibuprofen pain reliever and vitamin C nutritional supplement having labeling indicating an amount of vitamin C, which enables monitoring consumption of vitamin C while consuming ibuprofen, as

provided by the claimed method. [2] Krause (and the prior art of record) neither inherently provides, teaches, nor discloses a step or a functional relationship needed to enable monitoring vitamin C consumed with ibuprofen, or monitoring vitamin C consumed with ibuprofen, as provided by the claimed method. And, it neither inherently provides, teaches, nor discloses a) labeling an amount of vitamin C in a dose of ibuprofen, b) a functional relationship between labeling and vitamin C in the dose of ibuprofen, c) a product having a dose of ibuprofen and labeling of the amount of vitamin C in the dose, or d) consuming the dose from the labeled product, as provided by the claimed method. Therefore, Krause teaches away by neither monitoring nor enabling monitoring vitamin C consumption, (2) leading in a direction divergent from of path taken by Applicant in the claimed method of monitoring vitamin C consumption by labeling the amount of vitamin C in a dose of ibuprofen, which provides a functional relationship between labeling and vitamin C in the dose, and enables monitoring and regulation of consumption of the vitamin C, while consuming the dose of ibuprofen. Consequently, Krause teaches away leading in a direction divergent from (2) the path that was taken and (3) a result sought by (A) the elected claimed method of monitoring consumption of vitamin C with ibuprofen, (B) the product required by the elected claimed method having labeling indicating the amount of vitamin C in a dose of ibuprofen, (C) the step of the elected claimed method of labeling the amount of the vitamin C in a dose of ibuprofen, (D) the step of the elected claimed method of consuming the dose from the labeled enclosure, (E) the step of the elected claimed method of monitoring the vitamin C consumed, and (F) the result of the elected claimed method of enabling regulation of consumption of vitamin C, while consuming the dose of ibuprofen.

[3] The elected claimed method for monitoring consumption of vitamin C with ibuprofen by labeling a product with the amount of vitamin C in a dose of ibuprofen, consuming the dose from the labeled product, and monitoring the vitamin C consumed, is not obvious since: i) the elected claimed method and the steps of the elected claimed method and the functional relationship needed by the elected claimed method are not disclosed in the prior art of record, ii) the

prior art of record teaches away from the elected claimed method and its desired results, and iii) the claimed method satisfies a long felt need. The labeling and its functional relationship to the vitamin C in the dose of ibuprofen are new and unobvious making the elected claimed method of monitoring consumption of vitamin C in a dose of ibuprofen patentable. Consequently, it follows that the elected claimed method of monitoring consumption of vitamin C using the product labeled to indicate the amount of vitamin C in a dose of ibuprofen is not obvious, especially in view of Krause, which discloses food labeling, but does not disclose labeling the amount of vitamin C in a dose of ibuprofen, or a functional relationship between labeling and an amount of vitamin C in a dose of ibuprofen, or monitoring vitamin C consumed with the dose of ibuprofen. And, the elected claimed method is not obvious, since it cures defects of an ibuprofen product in use for decades. The step of the elected claimed method of labeling indicating the amount of vitamin C in a dose of ibuprofen provides a nonobvious functional relationship to the vitamin C in the dose, which enables monitoring vitamin C consumption, and cures defects of a product in use for decades. The claimed method produces the desired result of enabling consumers to regulate their consumption of vitamin C.

[VII] It would not be obvious to one of ordinary skill in the art at the time of the invention to monitor vitamin C consumed in a dose of ibuprofen, as provided by the claimed method, while administering the ibuprofen composition of Yeh et al for treating pain, since they do not disclose monitoring consumption of vitamin C, or enable it. They do not disclose labeling indicating an amount of vitamin C in a dose of ibuprofen, or a functional relationship between labeling and vitamin C in a dose of ibuprofen, which are needed for monitoring consumption of vitamin C. Administering the ibuprofen composition of Yeh et al for treating pain does not provide, teach or suggest a) a method of monitoring consumption of vitamin C with ibuprofen, as provided by the claimed method, b) an ibuprofen product having labeling indicating an amount of vitamin C, which is needed to enable monitoring vitamin C consumption, c) the labeling, consuming or monitoring steps of the claimed method, or d) the result of the claimed method of enabling

the consumer to regulate consumption of vitamin C, while consuming the dose of ibuprofen. Monitoring vitamin C consumption, as provided by the claimed method, would not be obvious to one of ordinary skill in the art at the time of the invention, by administering the ibuprofen composition of Yeh et al for treating pain, since the prior art of record discloses labeling the amount of ibuprofen in a dose of ibuprofen, but it does not disclose labeling an amount of vitamin C in a dose of ibuprofen, or a functional relationship between labeling and vitamin C in a dose of ibuprofen, which are needed to monitor vitamin C consumption. Yeh et al teach away (2) leading in a direction divergent from of path taken by Applicant, by disclosing a dose of ibuprofen, but without either inherently providing, teaching, or disclosing a) monitoring vitamin C consumed with ibuprofen or enabling it, as are provided by the elected claimed method or b) labeling an amount of vitamin C in a dose of ibuprofen, or c) a functional relationship between labeling and vitamin C in the dose of ibuprofen, which are needed for monitoring consumption of vitamin C in a dose of ibuprofen. Yeh et al do not disclose or enable monitoring vitamin C consumed with ibuprofen by disclosing a dose of ibuprofen, since they do not disclose a) monitoring consumption of vitamin C, or b) labeling an amount of vitamin C in a dose of ibuprofen, or c) a functional relationship between the labeling and vitamin C in the dose, which are needed for monitoring consumption of vitamin C in a dose of ibuprofen. Consequently, they teach away suggesting a line of development that is unlikely to produce the (3) results sought by Applicant, of enabling the consumer to regulate consumption of vitamin C, by a method for monitoring consumption of vitamin C in a dose of ibuprofen from an enclosure having labeling, which is functionally related to the amount of vitamin C in the dose of ibuprofen.

[VIII] Labeling of commercial ibuprofen does not indicate any percent daily value or amount of antioxidant, vitamin C or nutritional supplement. Monitoring vitamin C consumption, as provided by the elected claimed method, would not be obvious to one of ordinary skill in the art at the time of the invention, by administering the ibuprofen composition of the ibuprofen prior art of record or commercially available ibuprofen products for treating pain (Attachments B and

C), since they do not disclose labeling an amount of vitamin C in a dose of ibuprofen, or a functional relationship between labeling and vitamin C in a dose of ibuprofen, which are needed to monitor vitamin C consumption.

[IX] A) It would not have been obvious to one of ordinary skill in the art to employ the monitoring step of the elected claimed method, since the prior art of record and, commercially available ibuprofen products (Attachments B and C) do not disclose 1) monitoring consumption of vitamin C (or any other nutritional supplement) with ibuprofen, or 2) labeling the amount of vitamin C (or any other nutritional supplement) in a dose of ibuprofen and 3) a functional relationship between the labeling and the vitamin C (or any other nutritional supplement) in a dose of ibuprofen, which are needed to enable monitoring vitamin C consumed with ibuprofen.

B) A person of ordinary skill would be (1) discouraged from employing the monitoring step of the elected claimed method by following the path set out in Yeh et al, which neither inherently provides, teaches, nor discloses monitoring the amount of the vitamin C consumed in a dose of ibuprofen, or enable it by labeling the amount of the vitamin C in a dose of ibuprofen, and providing a functional relationship between labeling and vitamin C in the dose of ibuprofen.

C) The monitoring step of the elected claimed method and the functional relationship needed to carry it out are not disclosed by the prior art of record, which teaches away (A). A person of ordinary skill would be (1) discouraged from employing the monitoring step by following the path of the prior art of record, which neither inherently provides, teaches, discloses, nor enables it (B). The elected claimed method with its step of monitoring vitamin C consumption is enabled by the labeling step and the functional relationship between labeling and vitamin C in a dose of ibuprofen. Therefore, the elected claimed method with its step of monitoring vitamin C consumption is nonobvious and supportive of patentability, since it is not disclosed by the prior art of record, which teaches away from monitoring vitamin C consumed in a dose of ibuprofen and it i) satisfies a long felt need, ii) solves the problem, which others have failed to solve of not being able to monitor and regulate vitamin C consumed in ibuprofen pain

reliever.

D) It would not have been obvious to one of ordinary skill in the prior art of record to employ the monitoring step into a method to produce the result sought by Applicant of regulating vitamin C consumption, since the prior art of record (3) suggests development without monitoring the amount of vitamin C consumed with a dose of ibuprofen, or labeling the amount of vitamin C in a dose of ibuprofen and providing a functional relationship between the labeling and the vitamin C in a dose of ibuprofen, which are needed for monitoring vitamin C consumption. And, without monitoring vitamin C consumption it is unlikely to produce the results sought by Applicant of regulating vitamin C consumption, since monitoring vitamin C consumption is needed to regulate it.

[X] [1] One of ordinary skill in the art having been motivated to administer the analgesic composition of Yeh et al for treating pain, would not have been motivated to regulate vitamin C consumption, since it is not disclosed, or enabled. Yeh et al do not inherently provide, disclose or enable regulating vitamin C consumption, or monitoring vitamin C consumed in a dose of ibuprofen, or a) labeling the amount of vitamin C in a dose of ibuprofen, and b) a functional relationship between the labeling indicating the amount of vitamin C, and vitamin C in the unit dose of ibuprofen, which are needed to enable regulating vitamin C consumption. Consequently, one of ordinary skill in the art would not have been motivated to administer the analgesic composition of Yeh et al to produce the result of regulating vitamin C consumption sought by Applicant, since they do not disclose regulating vitamin C consumption, or enabling it. Rather, they teach away from regulating vitamin C consumption by (3) suggesting development unlikely to produce that result, by not disclosing it, or enabling it. Therefore, one of ordinary skill in the art would not have been motivated to regulate vitamin C consumption by administering the analgesic composition of Yeh et al for treating pain, since it is not inherently provided, disclosed or enabled. [2] Administering the analgesic composition of Yeh et al does not provide monitoring consumption of vitamin C, which is needed to regulate vitamin C consumption. And, it does not provide labeling the amount of

vitamin C in a dose of ibuprofen, and a functional relationship between the labeling and vitamin C in the dose, which are needed to monitor vitamin C consumption. Therefore, administering the analgesic composition of Yeh et al does not provide motivation for regulating vitamin C consumption, since it does not enable monitoring vitamin C consumption or regulating vitamin C consumption. Consequently, one of ordinary skill in the art being motivated to administer the analgesic composition of Yeh et al for treating pain does not suggest motivation for monitoring vitamin C consumption or regulating vitamin C consumption, since they are neither inherently provided, disclosed nor enabled.

[3] Administering the analgesic composition of Yeh et al does not enable monitoring vitamin C consumption, which teaches away by (2) leading in a direction divergent from of path taken by Applicant of monitoring vitamin C consumption by labeling the amount of vitamin C in a dose of ibuprofen, to provide a functional relationship between labeling and vitamin C in the dose, which enables monitoring consumption of the vitamin C. Administering the analgesic composition of Yeh et al, does not provide or enable the elected claimed method, since they do not disclose monitoring vitamin C consumption, or enabling it by: a) labeling an amount of vitamin C in a dose of ibuprofen, and b) providing a functional relationship between labeling and vitamin C in a dose of ibuprofen. And, administering the analgesic composition of Yeh et al does not enable regulating consumption of vitamin C, while consuming the dose of ibuprofen, since it requires monitoring consumption of vitamin C to regulate it. Rather, Yeh et al teach away by (3) suggesting a line of development of labeling ibuprofen, that is unlikely to produce the result sought by Applicant, of enabling regulation of vitamin C consumption, which requires a) monitoring consumption of vitamin C in a dose of ibuprofen, b) labeling an amount of vitamin C in the dose of ibuprofen, and c) providing a functional relationship between labeling and vitamin C in the dose. [4]The elected claimed method provides a new and unobvious functional relationship between labeling the amount of vitamin C in a dose of ibuprofen, and the vitamin C in the dose, which is needed to monitor consumption of vitamin C. And, administering the analgesic composition of Yeh

et al does not provide a functional relationship between labeling, and vitamin C in a dose of ibuprofen, which is needed to monitor vitamin C consumption, and is provided by the elected claimed method. [5] Administering the analgesic composition of Yeh et al does not inherently monitor or enable monitoring of vitamin C consumed with a dose of ibuprofen. It does not a) label an amount of vitamin C in a dose of ibuprofen, and b) provide a functional relationship between labeling and vitamin C in a dose of ibuprofen, which are needed to monitor vitamin C consumption. Consequently, a person of ordinary skill would be (1) discouraged from following the path of administering the analgesic composition of Yeh et al to monitor vitamin C consumption, (as provided by the elected claimed method), since the steps and functional relationship needed are not provided or enabled by administering the analgesic composition of Yeh et al.

[XI] Administering a composition of Yeh et al does not inherently provide or enable a method of monitoring vitamin C consumption, or any of the steps of the elected claimed method of a) labeling the amount of the vitamin C in a dose of ibuprofen, b) consuming the dose from the labeled enclosure and c) monitoring the vitamin C consumed. Administering a composition of Yeh et al (2) leads in a direction divergent from the path that was taken by Applicant, of monitoring of vitamin C consumption, since administering a composition of Yeh et al does not inherently provide or enable monitoring of vitamin C consumption, or the step of labeling amount of vitamin C in a dose of ibuprofen, and the functional relationship between labeling and vitamin C in a dose of ibuprofen, which are needed to carry out monitoring of vitamin C consumption. And, administering a composition of Yeh et al (3) suggests development unlikely to inherently produce the results sought by Applicant of enabling regulation of vitamin C consumption and regulating vitamin C consumption, since it does not inherently monitor and regulate vitamin C consumption, or inherently enable monitoring and regulating vitamin C consumption, or inherently provide a functional relationship between labeling and vitamin C in a dose of ibuprofen pain reliever, which is needed to monitor and regulate vitamin C consumption. Administering the composition of Yeh et al does not inherently imbue one of ordinary skill in the art with knowledge

of the elected claimed method of monitoring vitamin C nutritional supplement consumed in a dose of ibuprofen pain reliever, or a functional relationship between labeling and vitamin C in a dose of ibuprofen pain reliever, which is needed to monitor the vitamin C consumed, when no prior art reference of record conveys or suggests that knowledge.

[XII] Applicant is entitled to patent the elected claimed method for monitoring consumption of vitamin C with ibuprofen by labeling a known composition, consuming a dose from the labeled product, and monitoring the vitamin C consumed, since i) the elected claimed method, its steps and the functional relationship needed to carry it out are not disclosed by the prior art of record, ii) the prior art of record teaches away from the claimed method, iii) the elected claimed method satisfies a long felt need, iv) the claimed method solves the problem, which others have failed to solve of not being able to monitor or regulate vitamin C consumption from consuming ibuprofen pain reliever, or make the invention of the elected claimed method. And, the labeling and its functional relationship to the vitamin C in the dose of ibuprofen are new and unobvious making the elected claimed method of monitoring consumption of vitamin C in a dose of ibuprofen patentable. Consequently, it follows that the elected claimed method of monitoring consumption of vitamin C by labeling a product enclosing a known ibuprofen composition is not obvious, especially in view of Krause, which discloses food labeling, but does not disclose labeling the amount of vitamin C in a dose of ibuprofen, a functional relationship between labeling and vitamin C in a dose of ibuprofen, or monitoring vitamin C consumed with the dose of ibuprofen. And, the elected claimed method is patentable, since it cures defects of a product in use for decades. The step of the elected claimed method of labeling indicating the amount of vitamin C in a dose of ibuprofen provides a nonobvious functional relationship between labeling and vitamin C in the dose, which enables monitoring vitamin C consumption, and cures defects of a product in use for decades. And, monitoring vitamin C consumption produces the desired result of enabling consumers to regulate their consumption of vitamin C.

[XIII] One of ordinary skill in the art would not have been motivated to employ

the step of monitoring of vitamin C, since the labeling system of the ibuprofen pain reliever prior art is not intended for patients to grasp and understand the daily regimen of regulating consumption of vitamin C nutritional supplement and thereby improve the adherence to the daily regimen. And, in order to be adherent to the daily regimen, the patients have to consciously "watch and check on" or monitor what he or she is taking (consumption): no more or no less than what labeling the amount of vitamin C describes in functional relation to the vitamin C in the dose of ibuprofen to enable monitoring the vitamin C consumed. Therefore, the monitoring step of the elected claimed method is not met by the disclosure of the Yeh et al, since the labeling system of the ibuprofen pain reliever prior art does not indicate the amount of vitamin C in a dose of ibuprofen, or provide a functional relationship between the labeling and vitamin C in the dose, and is not intended for patients to grasp and understand the daily regimen of regulating consumption of vitamin C and thereby improve the adherence to the daily regimen. And, the prior art of record (3) suggests development unlikely to produce the result sought by Applicant of regulating vitamin C consumption, since it does not disclose regulating vitamin C consumed with ibuprofen, or the functional relationship and steps needed for regulation of vitamin C consumption of: a) labeling the amount of vitamin C in a dose of ibuprofen, b) a functional relationship between labeling and the vitamin C in the dose of ibuprofen, and c) monitoring the vitamin C consumed. Neither labeling an amount of vitamin C (or any other nutritional supplement) in a dose of ibuprofen, nor monitoring ("watching and checking on") its consumption, are shown in the prior art of record or labeling of commercial products based thereon (Attachments B and C), as required by the elected claimed method.

The elected claimed method and the steps of the elected claimed method and the functional relationship needed by the elected claimed method are not disclosed in the prior art of record. The prior art of record teaches away from the claimed method and its desired results. The prior art of record does not disclose a method of monitoring consumption of vitamin C with ibuprofen, or labeling indicating the amount vitamin C in a dose of ibuprofen to enable monitoring